CERTIFICATE OF GRANT OF PATENT

In accordance with Section 24(2) of the Patents Act, 1977, it is hereby certified that a patent having the specification No 2329127 has been granted to KCI Medical Limited, in respect of an invention disclosed in an application for that patent having a date of filing of 9 September 1998 being an invention for "Surgical drape and suction head for wound treatment"

Dated this Sixteenth day of August 2000

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Comptroller-General of Patents,
Designs and Trade Marks.
UNITED KINGDOM PATENT OFFICE

THE ATTENTION OF THE PROPRIETOR(S) IS DRAWN TO THE IMPORTANT NOTES OVERLEAF

(12) UK Patent (19) GB (11) 2 329 127 (13) B

(54) Title of Invention

Surgical drape and suction head for wound treatment

(51) INT CL[7]; A61M 27/00, A61B 19/08, A61M 1/00

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09.09.1998

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(33) GB

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16.08.2000

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US5437651 A
US5437622 A

(58) Field of search

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INT CL[6] A61B 19/08 19/10, A61M 1/00 27/00
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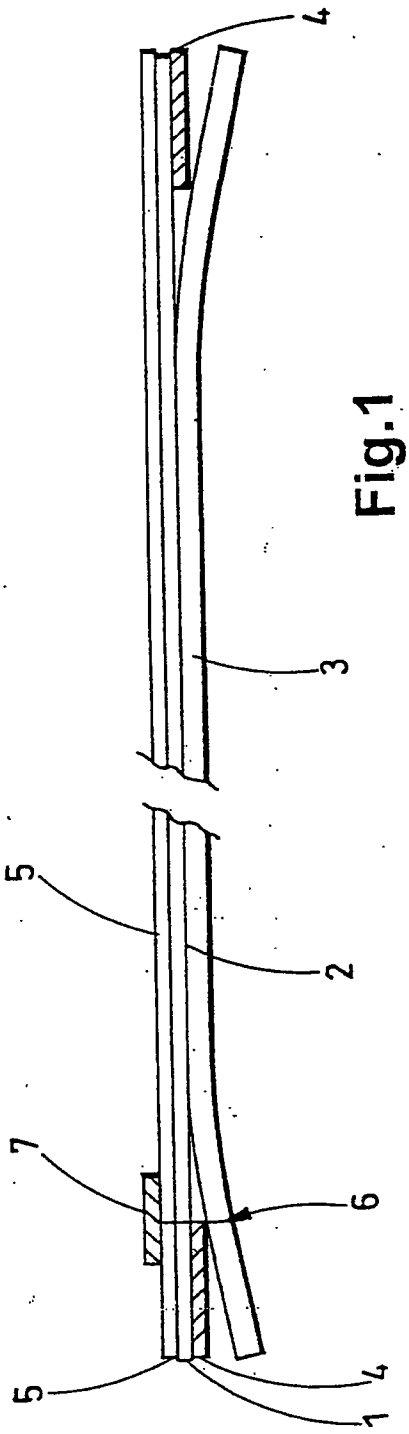

Fig.1

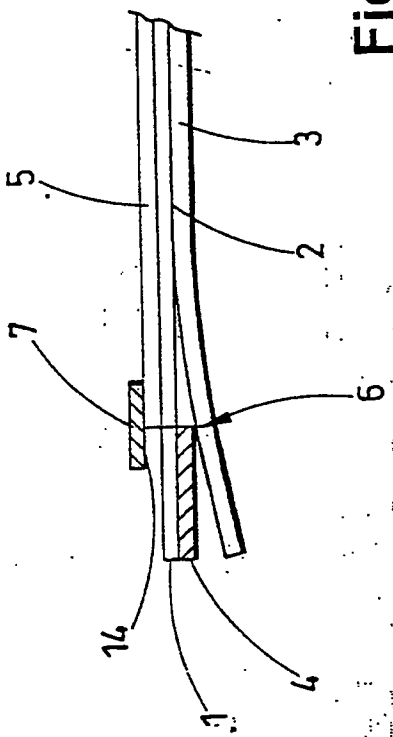

Fig. 2

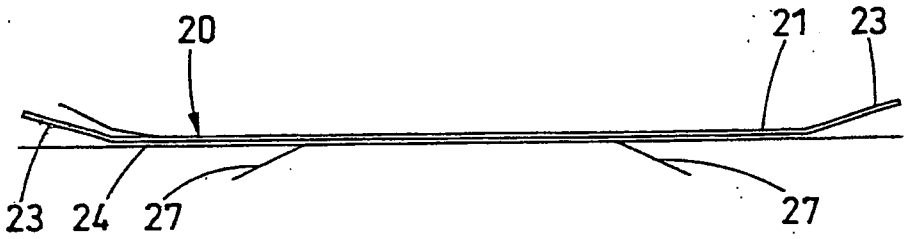

Fig. 3

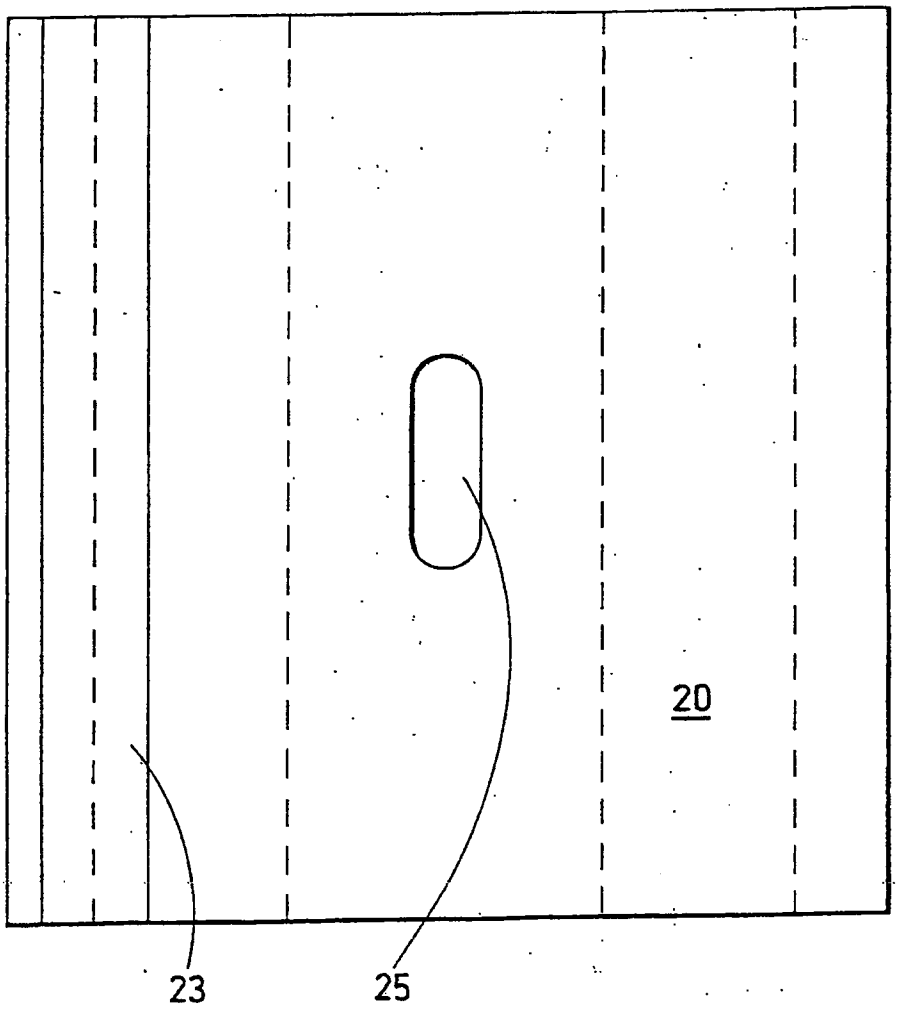

Fig. 4

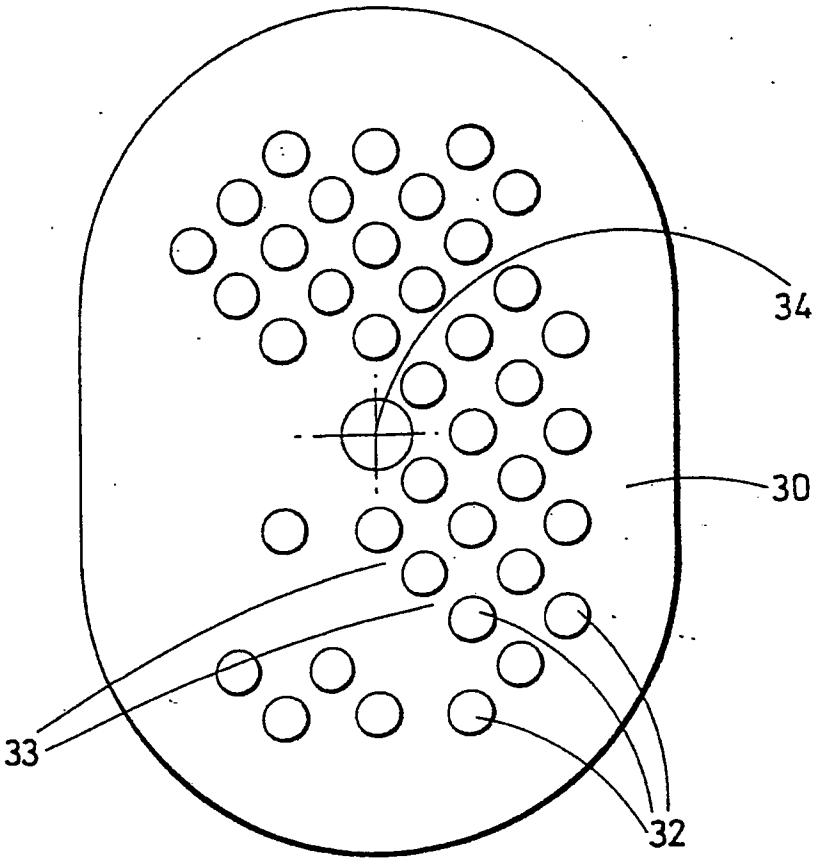

Fig. 5

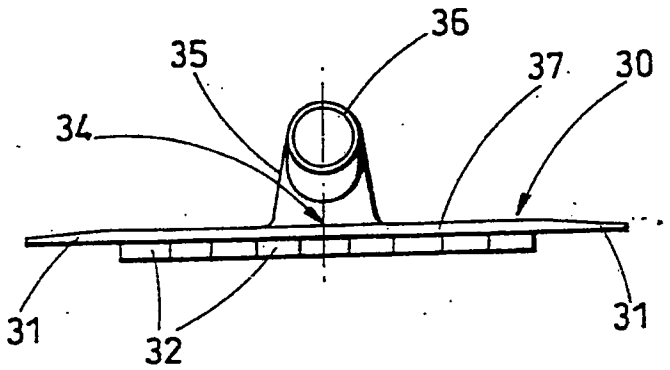

Fig. 6

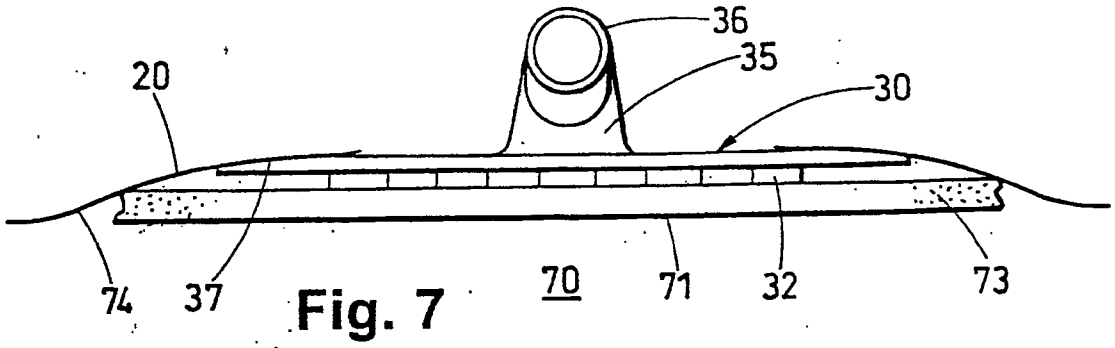

Fig. 7

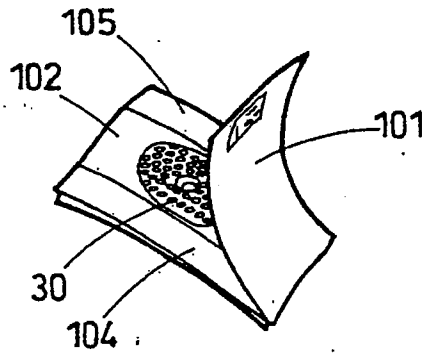

Fig. 8

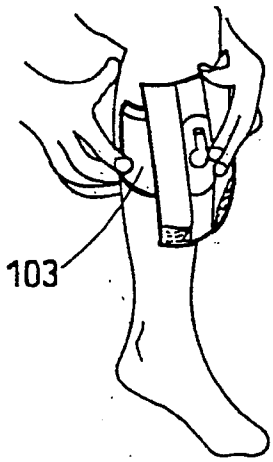

Fig. 9a

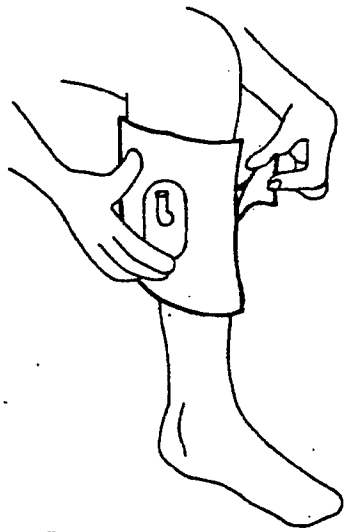

Fig. 9b

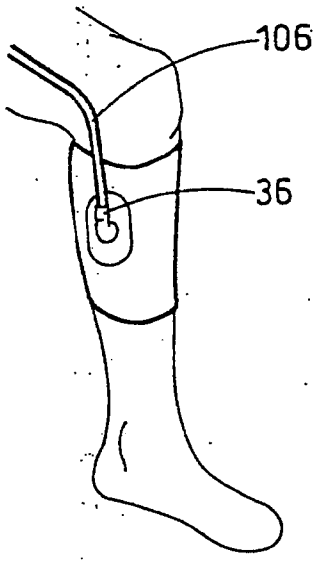

Fig. 9c

Surgical Drape and Suction Head for Wound Treatment

This invention relates to surgical drapes and suction heads for wound treatment.

Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are transparent or translucent. Typically, they consist of a flexible, plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

A further, recently developed use is for connecting a suction tube to a wound for the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible, plastics film is facilitated. For example, US Patent No. 5,437,622, describes a surgical drape which is a laminate of three materials. The first material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive-coated film is strengthened with a reinforcing layer of a less flexible, plastics film. Handling bars or strips are attached to the flexible, plastics film at its lateral edges to facilitate handling of the flexible, plastics film after stripping away the protective releasable layer.

Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose. It would be more convenient to have a surgical drape which was suitable without adaptation to accommodate the treatment device.

One aspect of the present invention is directed to a solution to this problem. A second aspect provides a combined surgical drape and suction head for applying suction to a wound area to facilitate application of negative pressure therapy.

According to one aspect of the present invention there is provided a suction head and surgical drape assembly for use with a source of suction for stimulating healing of an external wound wherein the suction head comprises a generally planar flange portion and a tubular connector portion on a first face for connecting a suction tube to an aperture extending through the flange portion to the other face, said other face having projections defining flow channels for facilitating flow of fluids towards the aperture, and wherein the surgical drape comprises a thin, flexible, adhesive-coated plastics film which is adhered to the first face and has an opening in the plastics film through which the tubular connector portion projects, the adhesive-coated film extending beyond the perimeter of the flange to enable the assembly to be adhered to the patient's skin around the wound, and wherein the adhesive-coating on the film is protected with a protective, releasable layer.

Preferably, the surgical drape comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening and adhesive-coated film to permit, in use, access to a wound area, a first edge of the drape having non-adhesive coated handling bars for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries a flap overlapping the adjacent portion

of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use. Preferably, non-adhesive-coated handling bars are positioned at opposite lateral edges of the drape.

In practice, surgical drapes may be manufactured by laminating an adhesive-coated flexible film, such as a polyurethane film, to a protective releasable layer, such as a siliconised paper. A strengthening layer of thicker plastics material, e.g. a polyolefin such as polyethylene, may be applied to the non-adhesive coated face of the flexible film, so that a three-layer laminate is produced. These laminates are produced in substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film

from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling characteristics are substantially improved by providing a protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

When negative pressure therapy is to be applied to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. The suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape affixed to the patient's skin. In this way, the suction head is held firmly in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open face of the foam pad and the drape applied over the suction head to fix the assembly to the patent's skin.

Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) or polyvinyl alcohol foams are preferred, especially when used as a pad which is placed over the wound. These latter foams are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

Further features and advantages of the present invention will be apparent from the following description and accompanying drawings, of non-limiting examples in accordance with the invention.

Referring to the accompanying drawings:-

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape for use in an assembly in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head for use in the assembly in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)~9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus,

by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein, the disclosure of which is incorporated herein.

Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

In the embodiments shown in Figures 3 and 4, the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the patient's skin with the peripheral areas of exposed adhesive-coated film.

An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31. The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may

be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

Figures 8 and 9(a)-(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam paid, the drape being adhered to the skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

CLAIMS:-

1. A suction head and surgical drape assembly for use with a source of suction for stimulating healing of an external wound wherein the suction head comprises a generally planar flange portion and a tubular connector portion on a first face for connecting a suction tube to an aperture extending through the flange portion to the other face, said other face having projections defining flow channels for facilitating flow of fluids towards the aperture, and wherein the surgical drape comprises a thin, flexible, adhesive-coated plastics film which is adhered to the first face and has an opening in the plastics film through which the tubular connector portion projects, the adhesive-coated film extending beyond the perimeter of the flange to enable the assembly to be adhered to the patient's skin around the wound, and wherein the adhesive-coating on the film is protected with a protective, releasable layer.

2. A suction head and surgical drape assembly as claimed in claim 1 in which the adhesive-coated film is strengthened with a second plastics film which is thicker or less flexible than said adhesive coated film.

3. An assembly as claimed in claim 2 wherein said releasable layer comprises a separate strip protecting the adhesive coating in the vicinity of the suction head and said strip carries a flap overlapping an adjacent portion of the releasable layer and constituting a handle to facilitate removal of said strip prior to use.

4. An assembly as claimed in claim 3 wherein at least one first edge of the drape has a non-adhesive coated handling bar for separating the protective layer from the adhesive-coated film, and wherein the protective layer comprises a separate strip extending parallel to the first edge and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping an adjacent portion of

the protective layer, said flap constituting a handling bar for facilitating removal of said strip prior to use.

5. An assembly as claimed in claim 4 wherein handling bars are positioned at opposite lateral edges of the drape.

6. An assembly as claimed in any one of the preceding claims in which the flange portion has a generally rounded perimeter.

7. An assembly as claimed in any one of the preceding claims which includes a foam pad of open-celled polymer foam in contact with said other face of the flange portion.

8. An assembly as claimed in claim 7 in which the foam pad extends beyond the perimeter of the flange portion of the suction connector.

9. An assembly as claimed in claim 7 or 8 wherein the foam is a polyvinyl alcohol foam.

10. An assembly as claimed in any one of the preceding claims wherein a catheter is connected to the tubular connector portion, the tubular portion being formed with an internal projection or slot which cooperates with a corresponding slot or projection on the catheter.

BALANCE DEVICE

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Publication date:	1992-04-30
Inventor:	KEINO HIROYOSHI
Applicant:	TERUMO CORP
Classification:	
- international:	A61B5/14; A61M1/02; G01G17/04
- european:	
Application number:	JP19900247288 19900919
Priority number(s):	JP19900247288 19900919

Abstract of **JP4129536**

PURPOSE:To obtain a balance device with which the balance precision is improved, by correcting the detection error of a weight detecting means which is caused by the tilt of a container supporting part, according to the tilt of the container supporting part, and installing a control means for obtaining the weight in a container on the container supporting part. CONSTITUTION:As for a blood taking device 10, a bag receiving plate 19 is supported on a balance 33 which is cantilever-supported through a balance installation member 31, and the CPU 65 of a main control circuit 61 detects the weight of a blood bag 1 on the bag receiving plate 19 in the vertical direction for the hag receiving plate, from the output V2 of a weight detecting sensor 34 consisting of a strain guage on the basis of the torsional deformation of the balance 33. Further, the CPU 65 of the main control circuit 61 calculates the tilt angle theta which the bag receiving plate 19 forms for the vertical direction in the case when a weight detection sensor 34 detects weight, from the output V1 of a tilt detection sensor 100 installed on the bag receiving plate 19 or a swing frame 22. The CPU 65 of the main control circuit 61 detects the correct weight of the blood bag 1 by correcting the output V2 of the weight detection sensor 34 by using the tilt angle theta, and the blood taking-in quantity is measured.

THE REGISTRY OF PATENTS
SINGAPORE

THE PATENTS ACT
(CHAPTER 221)

CERTIFICATE OF GRANT OF PATENT

In accordance with section 35 of the Patents Act, it is hereby certified that a patent having the following P-No. 71559 [WO 99/13793] had been granted in respect of an invention having the following particulars:

Title	:	SURGICAL DRAPE AND SUCTION HEAD FOR WOUND TREATMENT
Application No.	:	200001315-1
Date of Filing	:	09 September 1998
Priority Data	:	12 September 1997 - PATENT APPLICATION NO. 9719520.0(UNITED KINGDOM)
Name of Inventor(s)	:	HEATON, KEITH, PATRICK; HUNT, KENNETH, WILLIAM
Name(s) and Address(es) of Proprietor(s) of Patent	:	KCI MEDICAL LIMITED (INCORPORATED IN UNITED KINGDOM) TWO RIVERS STATION LANE WITNEY OXFORDSHIRE OX8 6BH, UNITED KINGDOM
Date of Grant	:	16 April 2002

Dated this 16th day of April 2002.

Liew Woon Yin (Ms)
Registrar of Patents,
Singapore.

INFORMATION SHEET

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TERM OF PATENT	20 Years
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WORKING	Not Compulsory
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(71) Applicant *(for all designated States except US)*: KCI MEDICAL LIMITED [GB/GB]; Two Rivers, Station Lane, Witney, Oxfordshire OX8 6BH (GB).

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(74) Agent: WOODCRAFT, David, Charles; Brookes & Martin, High Holborn House, 52/54 High Holborn, London WC1V 6SE (GB).

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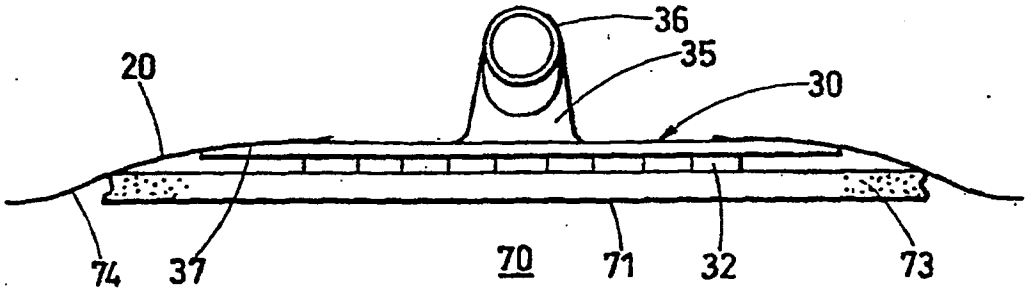
Published
With international search report.

(54) Title: SURGICAL DRAPE AND SUCTION HEAD FOR WOUND TREATMENT



(57) Abstract

This invention relates to surgical drapes and in particular provides a drape and suction head combination for attaching the suction head to a wound area. The suction head comprises a planar flange portion and a tubular connector piece on a first face which communicates with an aperture extending to the second face. The second face is formed with projections which define flow channels for facilitating flow of liquids to the aperture.

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Surgical Drape and Suction Head for Wound Treatment

This invention relates to surgical drapes and suction heads for wound treatment.

Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are transparent or translucent. Typically, they consist of a flexible, plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

A further, recently developed use is for connecting a suction tube to a wound for the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible, plastics film is facilitated. For example, US Patent No. 5,437,622, describes a surgical drape which is a laminate of three materials. The first material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive-coated film is strengthened with a reinforcing layer of a less flexible, plastics film. Handling bars or strips are attached to the flexible, plastics film at its lateral edges to facilitate handling of the flexible, plastics film after stripping away the protective releasable layer.

Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose. It would be more convenient to have a surgical drape which was suitable without adaptation to accommodate the treatment device.

One aspect of the present invention is directed to a solution to this problem. A second aspect provides a combined surgical drape and suction head for applying suction to a wound area to facilitate application of negative pressure therapy.

According to one aspect of the present invention there is provided a surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening and adhesive-coated film to permit, in use, access to a wound area, a first edge of the drape having non-adhesive coated handling bars for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries a flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use. Preferably, non-adhesive-coated handling bars are positioned at opposite lateral edges of the drape.

In practice, surgical drapes may be manufactured by laminating an adhesive-coated flexible film, such as a polyurethane film, to a protective releasable layer, such as a siliconised paper. A strengthening layer of thicker plastics material, e.g. a polyolefin such as polyethylene, may be applied to the non-adhesive coated face of the flexible film, so that a three-layer laminate is produced. These laminates are produced in substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film

from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling characteristics are substantially improved by providing a protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

In a preferred form of the invention in which negative pressure therapy is applied to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. Thus, in this embodiment, the suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape affixed to the patient's skin. In this way, the suction head is held firmly in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

The invention also includes a suction head having a design which facilitates the suction of fluid from a wound area.

According to a further feature of the invention, therefore, there is provided a suction head for applying suction to a wound area which comprises a generally planar

flange portion and a tubular connector piece on a first face, for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels facilitating flow of fluid towards said aperture.

Preferably, the suction head described above is combined with a surgical drape, the drape comprising a thin, flexible, adhesive-coated plastics film, and the tubular connector piece extends through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open face of the foam pad and the drape applied over the suction head to fix the assembly to the patent's skin.

Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound. These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

Further features and advantages of the present invention will be apparent from the following description and accompanying drawings, of non-limiting examples in accordance with the invention.

Referring to the accompanying drawings:-

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)~9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus,

by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein, the disclosure of which is incorporated herein.

Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

In the embodiments shown in Figures 3 and 4, the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the patient's skin with the peripheral areas of exposed adhesive-coated film.

An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31. The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may

be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

Figures 8 and 9(a)-(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam paid, the drape being adhered to the skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

CLAIMS:-

1. A suction head for applying suction to a wound area which comprises a generally planar flange portion and a tubular connector piece on a first face for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels for facilitating flow of fluids to said aperture.

2. A suction head as claimed in claim 1 which is combined with a surgical drape, the drape comprising a thin, flexible adhesive-coated plastics film, the tubular connector piece extending through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

3. A suction head and surgical drape combination as claimed in claim 2 in which the adhesive-coated film is strengthened with a second plastics film which is thicker or less flexible than said adhesive coated film.

4. A suction head and surgical drape combination as claimed in claim 2 or 3 wherein the adhesive coating on said flexible film is protected with a protective, releasable layer covering the area of the adhesive, said releasable layer comprising a separate strip protecting the adhesive coating in the vicinity of the suction head and said strip carrying a flap overlapping an adjacent portion of the releasable layer and constituting a handle to facilitate removal of said strip prior to use.

5. An assembly for use with a source of suction for stimulating healing of wounds which comprises a foam pad comprising an open-celled flexible polymer foam and a suction head and drape as claimed in claim 4

6. A surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the

adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

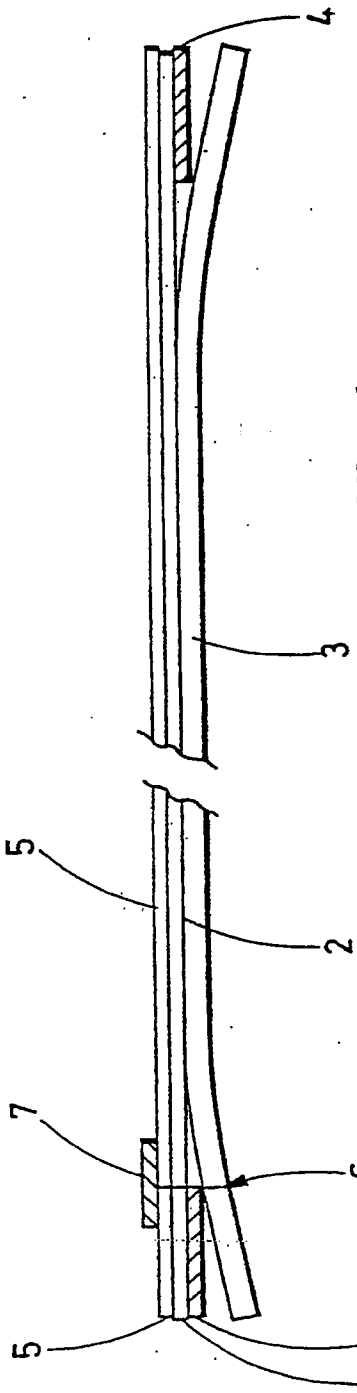

Fig.1

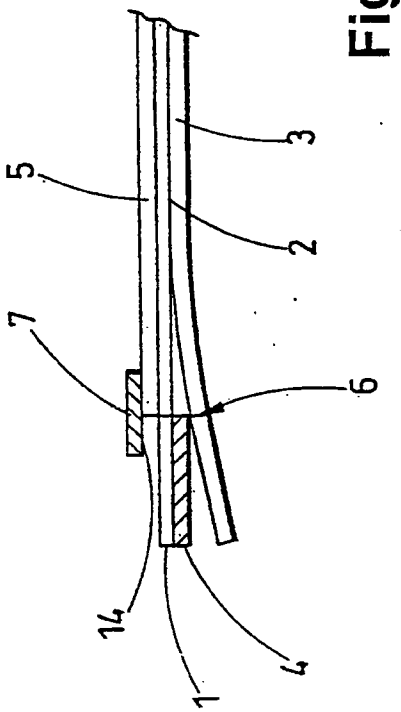

Fig. 2

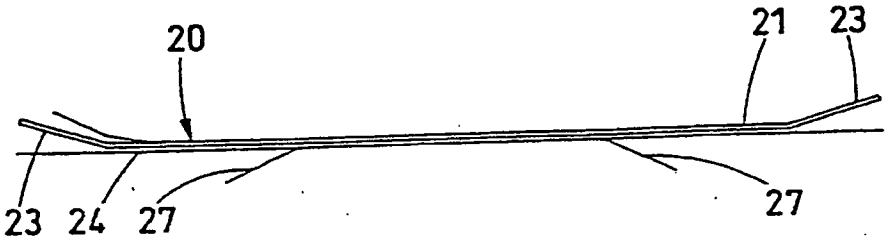

Fig. 3

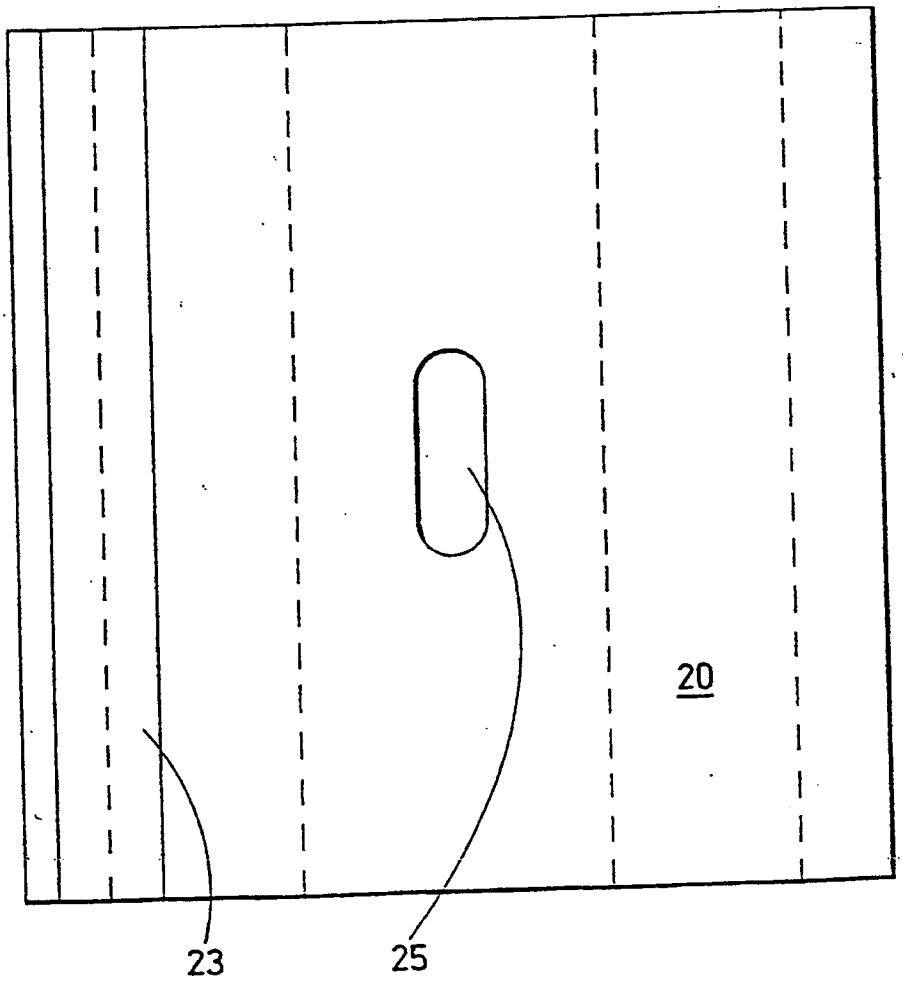

Fig. 4

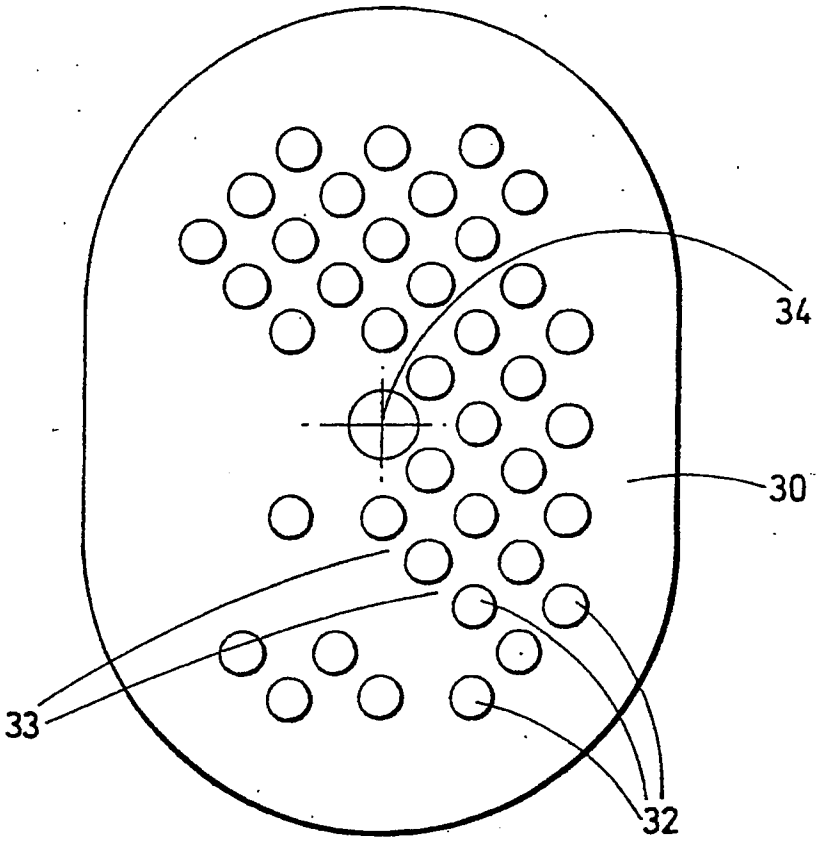

Fig. 5

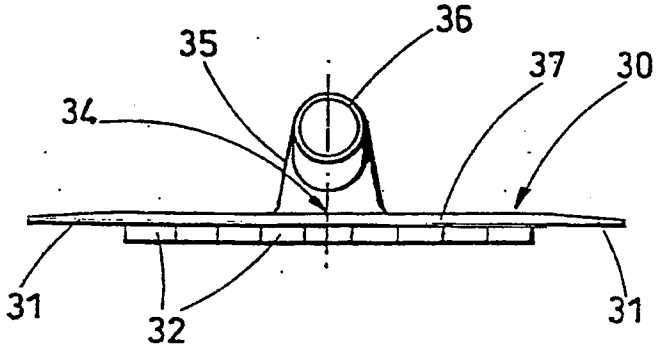

Fig. 6

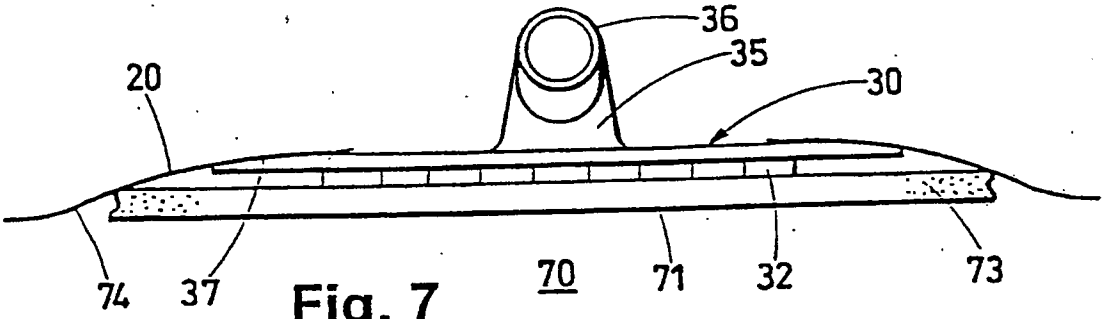

Fig. 7

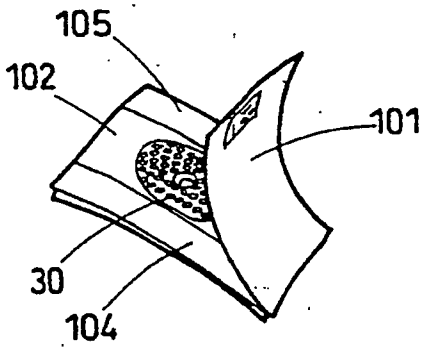

Fig. 8

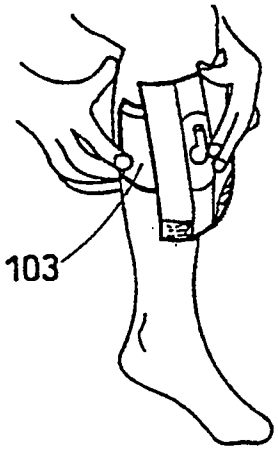

Fig. 9a

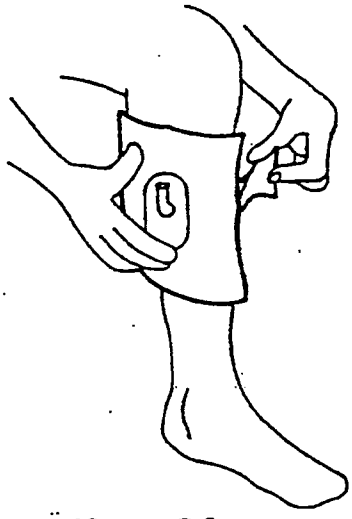

Fig. 9b

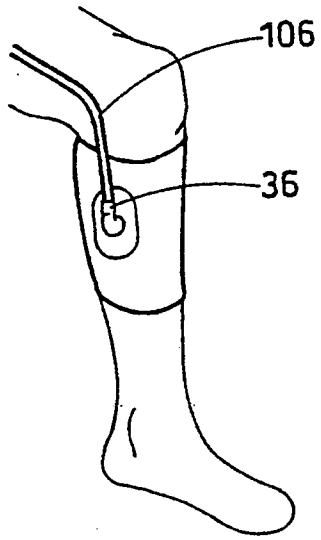

Fig. 9c

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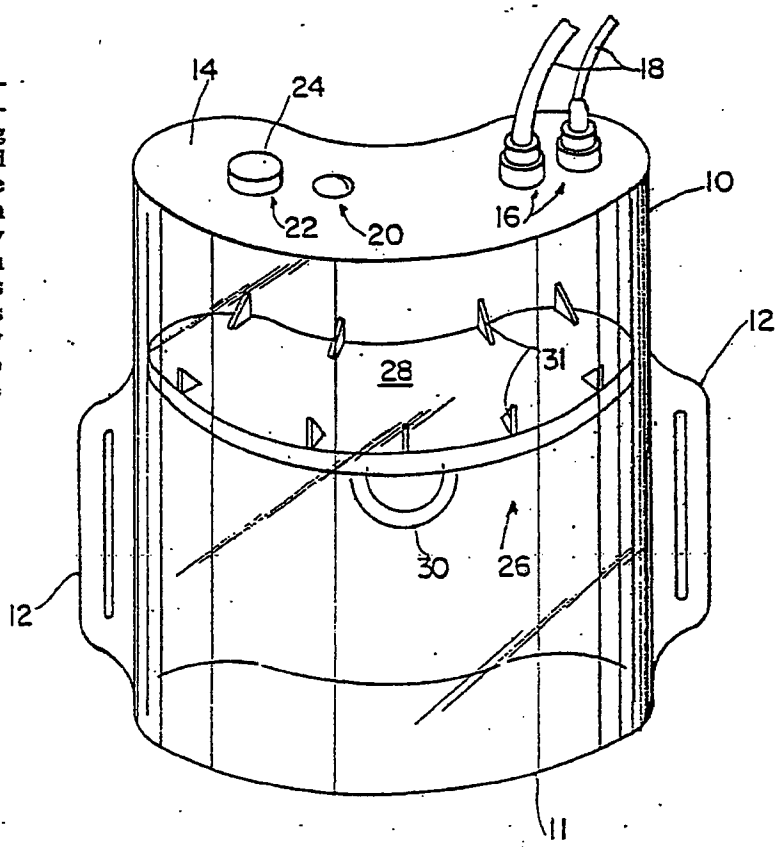
(54) Title: PORTABLE SUCTION DEVICE FOR COLLECTING FLUIDS FROM A CLOSED WOUND

(57) Abstract

A portable closed wound suction device is provided which is adapted to be worn on the body following outpatient and other limited surgical procedures. Specifically, the device provides a rigid container (10) which is adapted to be strapped to the body of a patient with a tubular connection (18) to a wound for collecting fluids from the wound. The container (10) is provided with a wall (28) which may be moved from an inactive position to a locked outer position so as to create suction within the device.



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PORTABLE SUCTION DEVICE FOR COLLECTING FLUIDS FROM A CLOSED WOUND

TECHNICAL FIELD

The invention relates to a portable closed wound suction device and more particularly, to such a device which may be worn by persons following outpatient surgery and which provides suction to remove fluids from a closed wound in a rigid container having no movable parts which could be tampered with by the patient.

BACKGROUND ART

Due to the large increase in recent years in outpatient surgery, there has developed a substantial need for portable collection chambers which may be used with a surgical drain to permit the efflux of blood, serum and body secretions from the operative site to the exterior of the patient. Heretofore, such collection chambers could not be used effectively for outpatient care for the reason that such devices were too bulky to be portable or such devices incorporated movable parts, valves or the like which could be tampered with by the patient so as to render the device inoperative or even to cause body fluids secreted from the wound to be forced back into the body. Thus, there exists a need for a truly portable closed wound suction device which is constructed in such a way that the proper operation of the device cannot be interfered with in any way by the patient.

Typically, prior art devices which are designed for portable closed wound suction are shown in patents 3,115,138 and 3,376,868. Such device provide a moveable wall or container formed as a bellows which are adapted to be compressed to create a suction therein as the device returns to its original configuration. However, if such devices are accidently compressed by the patient when partially filled, the potentially contaminated body

fluids which have been drawn from the wound site will be forced back into the wound area. Other devices such as shown, for example, in patents 3,900,029 or 3,774,811 are too bulky to be considered adapted to be worn by a patient as a portable unit in the home environment after outpatient surgery.

Numerous attempts have been made in the prior art to provide a reliable suction collection chamber which could be activated by the surgeon following surgery and carried by the patient in the hospital while the wound is healing, but such prior art devices have not met all of the essential criteria set forth hereinbefore, that is, providing a readily portable unit which is formed as a rigid container with no valves, bulbs or movable parts which can be tampered with by the patient.

SUMMARY OF THE INVENTION

The present invention provides a closed wound suction device formed as a container with rigid top and side walls. The bottom wall is movably mounted in sealing engagement with the interior of the container so that it can be moved from a first inoperative position adjacent the top wall of the unit to an operative locked position in substantial spaced relation to the top wall, in which position suction is created within the unit. The container is provided with tube connections by which tubes can be connected with the wound site in a conventional manner. The device is shaped so that it may be readily strapped to the body of the patient adjacent the wound site and the rigid wall construction, including the locked in place bottom wall, does not permit the patient to alter in any way the operation of the device.

There may be provided a diaphragm in the top wall of the collection container to permit taking a sample of the fluid within the container or for removing the fluids within the container for continued use by the

patient. Furthermore, there may be provided a suction indicator which serves to indicate the degree of suction existing within the container. The handle or means by which the bottom wall is drawn down to its suction creating position may be removed after the bottom wall is locked in its operative position.

Thus, according to the present invention there is provided a rigid container with substantially non-compressible walls which is readily adaptable to be strapped to the body of a patient and which, when in the operative condition, has no movable parts, valves or bulbs which would permit the patient to alter the correct operative conditions of the unit.

A primary object of the present invention, therefore, is to provide a portable closed wound suction device which is particularly well suited for out-patient care.

Another object of the present invention is to provide a rigid wall collection chamber for closed wound suction which is adapted to be strapped to the patient's body which is not subject to being tampered with by the patient.

Other objects and attendant advantages will become more readily apparent upon consideration of the following detailed drawings and description.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of one embodiment of the present invention comprising a collection container with a movable bottom wall.

Figure 2 is a cross-sectional view of a similar embodiment of the present invention depicted in Figure 1 with the movable bottom wall in a retracted position.

Figure 3 is a cross-sectional view of the embodiment of the present invention depicted in Figure 2 with the movable bottom wall locked in an extended position.

Figure 4 is a cross-sectional view of another embodiment of the present invention with a rigid bottom wall and a movable rigid wall plug.

Figure 5 is a cross-sectional view taken along the line 5-5 in Figure 4.

Figure 6 is a top view of the embodiment depicted in Figure 4.

Figure 7 is a cross-sectional view of still another embodiment of the present invention with a deflated balloon located inside of the rigid container.

Figure 8 is a cross-sectional view of the embodiment depicted in Figure 7 with the movable wall in an extended position and with an inflated balloon inside the container.

DETAILED DESCRIPTION

With reference now to the drawings in which like numerals represent like elements throughout the several views, a presently preferred embodiment of the present invention is depicted in Figure 1 and comprises a rigid container 10 with an open end 11. In order to view the amount of fluid collected in rigid container 10, rigid container 10 is preferably made of a transparent plastic. Rigid container 10 is bow-shaped so that it can be comfortably worn on the body of the user by means of a belt or the like which passes through flanges 12 located on the sides of rigid container 10. Located on top wall 14 of rigid container 10 is port means 16. Port means 16 has drainage tubes 18 attached thereto. Also located on top wall 14 is a suction indicating means 20 and an aspiration port means 22 covered by a cap 24.

Rigid container 10 has a closure means 26 which consists of a movable rigid wall 28 with a pull tab 30. A plurality of spacers 31 placed near the edges of rigid wall 28 prevent rigid wall 28 from pressing against top wall 14.

Referring now also to Figures 2 and 3, an embodiment of the present invention, similar to the one depicted in Figure 1, is shown. This embodiment has a pair of port means 16 which can receive different sizes of drainage tubes 18. Upstanding rubber nipple 32 is attached to the top wall 14 of rigid container 10. Rubber nipple 32a can receive a very small drainage tube 18 in orifice 34. If a slightly larger drainage tube 18 is desired, orifice 14 can be easily cut off of rubber nipple 32a so that orifice 35 receives the slightly larger drainage tube 18. Likewise, orifice 35 can be removed so that orifice 36 can accomodate a still larger drainage tube 18. Rubber nipple 32b is initially closed at the top, but rubber nipple 32b can similarly be trimmed to receive different sized catheters. Extending below each rubber nipple 32 is a one way valve 36 formed of resilient fingers normally biased together but which open to permit fluid flow into rigid container 10.

Suction indicating means 20 is used to determine when a negative pressure exists inside of rigid container 10. A small latex disc 38 is attached over opening 40 to form an airtight seal. When a negative pressure does exist inside of rigid container 10, latex disc 38, which normally protrudes slightly outwardly of rigid container 10 as shown in Figure 2, is pulled slightly toward the inside of rigid container 10 as shown in Figure 3.

Aspiration port means 22 is used to withdraw a sample of the liquid which is collected in rigid container 10. Aspiration port 44 in top wall 14 is covered by a puncturable flap 46 made of rubber or the like. Surrounding flap 46 is upstanding wall 48 having exterior screw threads. Cap 24 with mating screw threads and a gasket 50 is normally screwed down on upstanding wall 48 to create a fluid-right seal. When a fluid sample is desired, cap 24 is removed and a syringe is inserted into rigid container 10 through flap 46 and aspiration

port 44. Flap 46, which may leak slightly due to previous punctures, acts to preserve the negative pressure inside of rigid container 10 while cap 24 is temporarily removed.

Closure means 26 is shown in Figure 2 in its retracted inoperative position, while in Figure 3 closure means 26 is shown in its extended operative position. A rigid wall 28 with an annular gasket 54 around its periphery forms a closure means 26. Rigid wall 28 is also bow shaped so that it mates with the walls of rigid container 10 to form an airtight seal. A plurality of upstanding spacers 31 are mounted on rigid wall 28 to keep rigid wall 28 in proper alignment as it is moved. Spacers 31 assure that a small air pocket is maintained between rigid wall 28 and top wall 14 and prevents rigid wall 28 from engaging and damaging check valves 36.

In order to draw rigid wall 28 from its retracted position to its extended position, a detachable handle 30 is provided. Detachable handle 30 is attached to rigid wall 28 by means of a key 56 on detachable handle 30 which engages a mating keyway 58 in rigid wall 28. Detachable handle 30 is attached to rigid wall 28 by inserting key 56 into keyway 58 and then turning handle 30 counterclockwise approximately 90°. Handle 30 is easily detached in a like manner by turning handle 30 in a clockwise direction.

Depending from rigid wall 28 are two arms 60 with attached shoulder portions 62. Each arm forms a resilient element which urges shoulder portion 62 outwards. On the side walls of rigid container 10 near open end 11 are recesses 64 which mate with shoulder portions 62. As rigid wall 28 is drawn towards open end 11 by handle 30, shoulder portions 62 are resiliently urged outward and engage recesses 64. This locks rigid wall 28 in place, preventing rigid wall 28 from moving inward or outward.

In operation, the portable closed wound suction device functions in the following manner. First, drainage tube 18 with a suitable catheter on its distal end is inserted into the closed wound which needs to be drained. The proximal end of drainage tube 18 is then inserted in rubber nipple 32 after rubber nipple 32 has been trimmed (if necessary) to the proper sized orifice 34, 35 or 36. A second drainage tube can also be used in a similar manner with the second rubber nipple 32. Normally with two nipples 32 one is manufactured open and the other closed so that one drain is always inserted in the open inlet and, if a second drain is desired, the tip of the second inlet is cut off by the surgeon and the drain inserted. Then, with cap 24 in place over aspiration port 44, the wound suction device is activated when pull tab 30 moves rigid wall 28 from its retracted inoperative position as shown in Figure 2 to its extended operative position as shown in Figure 3. When rigid wall 28 reaches open end 11 of rigid container 10, shoulder portions 62 which are resiliently urged outward by arms 60 lock into recesses 64 and hold rigid wall 28 firmly in place. As rigid wall 28 is drawn downward, annular gasket 54 forms a fluid tight seal against the walls of rigid container 10 so that a negative pressure is created and maintained inside of rigid container 10. This negative pressure causes any fluids located around the catheter to be drawn or sucked through drainage tube 18 and check valve 36 into the interior of rigid container 10. The negative pressure also draws or sucks latex disc 38 inward towards the interior of rigid container 10 so that latex disc 38 acts as a suction indicating means.

In use by the patient, the closed wound suction device is designed to be worn around the wrist by means of a belt or the like which passes through flanges 12. The bow shape of the device makes it more comfortable to

wear. This device is also designed so that the patient cannot tamper with it while the patient is wearing it. Therefore, after rigid wall 28 is locked in its extended position, pull tab 30 is removed by turning it approximately 90° and withdrawing key 56 from keyway 58 in rigid wall 28. This leaves only a rigid walled container so that the patient has nothing with which to tamper which could vary the negative pressure inside of rigid container 10.

After some fluid is collected, some or all of it is removed through aspiration port means 22. To accomplish this, cap 24 is removed and the device is tilted so that the fluid collects in the corner near aspiration port 44. The tip of a syringe is then inserted through puncturable flap 46 to draw off some of the fluid. It should be noted that as the fluid is drawn off, the negative pressure inside of rigid container 10 is increased. Therefore if fluid accumulates to such a degree that the negative pressure inside rigid container 10 is appreciably decreased, the negative pressure can be restored by simply removing the fluid in this manner. Likewise, if it is desired to increase the negative pressure inside of rigid container 10, air can also be removed as well. After the fluid has been withdrawn, cap 24 is replaced in case puncturable flap 46 develops a small leak. It should also be noted that the fluid cannot flow backwards from the inside of the rigid container 10 to the wound because of check valves 36. If for some reason, such as the inrush of air occuring when the airtight seal is suddenly lost, the fluid is urged back into drainage tubes 18, check valves 36 close so as to prevent this. After the portable wound suction device has served its purpose, it must be disposed of because it cannot be reused as rigid wall 28 is locked in place and cannot be readily removed from its operative position.

A further embodiment of the present invention is depicted in Figures 4, 5 and 6. This embodiment is used when a smaller negative pressure inside of rigid container 10 is desired. In this embodiment, a bottom wall 70 closes part of rigid container 10. Thus, open end 11' of rigid container 10 is only a small circular portion of the total area of the bottom of the container. Upstanding from bottom wall 70 is an interior wall 72 which forms a cylindrical chamber 74 with a raised lip 76. Rigid wall 28' is a cylindrical plug with annular gaskets 54' surrounding rigid wall 28' so that rigid wall 28' forms an airtight fit inside of cylindrical chamber 74. Like the previously described embodiment, rigid wall 28' is engaged by a detachable pull tap (not shown). Rigid wall 28' also has shoulder portions 62' which are resiliently urged outward.

As detailed in the previously described embodiments, this embodiment also has a suction indicating means 20 comprising a latex disc 38 and an opening 40. Similarly, drainage tubes 18 are attached to rubber nipples 32 which have a common outlet 78 and check valve 36' in this embodiment. Also in this embodiment, aspiration port means 22 is recessed inside of rigid container 10 so that a puncturable cap 80 is flush with the top of top wall 14 when it covers aspiration port 44.

In operation, this embodiment functions in the same manner as the previously described embodiment. Thus, with drainage tubes 18 suitably attached to the patient and to rubber nipples 32', rigid wall 28' is moved from a retracted inoperative position to an extended operative position by a detachable pull tab. In the retracted position, shoulder portions 62' of rigid wall 28' are pulled over and then locked under lip 76. Because rigid wall 28' and cylindrical chamber 74 represent only a small portion of the inside of rigid container 10, only a small negative pressure is created

when rigid wall 28' is moved from its inoperative to operative position. This small pressure is still enough to pull latex disc 38 into opening 40 so that suction is indicated. Only a puncturable cap 80 need cover aspiration port 44, as puncturable cap 80 does not leak under the influence of such a small negative pressure even after the needle of a syringe has been passed through puncturable cap 80 to withdraw a sample of the fluid in rigid container 10.

Still another embodiment of a portable wound suction device which produces a smaller negative pressure in rigid container 10 is depicted in Figures 7 and 8. Like the first described embodiment, this embodiment has a rigid wall 28, which is the same size as top wall 14, with an annular gasket 54. In the same manner, rigid wall 28 is drawn from an inoperative to an operative position by a detachable pull tab 30". Rigid wall 28 is likewise locked in an operative position by outwardly urged shoulder portions 62" on arms 60 which engage lip 80". This embodiment also has two rubber nipples 32, with a common outlet 78 and check valve 36', which receive drainage tubes 18.

Located inside of rigid container 10 is an inflatable lubricated balloon 82. The open end of inflatable balloon 82 is mounted on a recessed portion of top wall 14 by a suitable sealing plug 86 so that a vent 84 provides fluid communication between the interior of balloon 82 and the surrounding atmosphere. In order to protect inflatable balloon 82 from the sharp needle of a syringe which is passed through puncturable cap 80 and aspiration port 44, a cup-shaped enclosure 88 is located below aspiration port 44. Cup-shaped enclosure 88 has a solid bottom wall and openings 90 in the side walls.

In operation, this embodiment functions in a similar manner to the previously described embodiment. After drainage tubes 18 are connected to the patient and

to the device, rigid wall 28 is pulled down and locked to its operative position by detachable handle 30". As this is occurring, air is drawn into inflatable balloon 82 through vent 84. Inflatable balloon 82, depending on its resiliency, inflates and fills a portion of the interior of rigid container 10. The negative pressure which is created inside of rigid container 10 between the walls of rigid container 10 and the inflatable balloon 82 will vary according to the volume to which inflatable balloon 82 is inflated. The resiliency of inflatable balloon 82 determines the volume to which it inflates. Therefore, if inflatable balloon 82 is very resilient, it will inflate to almost the entire volume of rigid container 10 and only a small negative pressure is created. Conversely, if inflatable balloon 82 is relatively non-resilient, it will inflate only slightly creating a larger negative pressure. By varying the resiliency of inflatable balloon 82, a variety of portable wound suction devices can be made available to provide for a choice of the negative pressures created. As fluid collects in rigid container 10, the negative pressure tends to remain the same as balloon 82 is resiliently urged back to its uninflated position.

In order to obtain a sample of the fluid contained in rigid container 10, rigid container 10 is tilted until the fluid is located in the corner near the aspiration port 44. The fluid flows into cup-shaped enclosure 88 through openings 90. When the needle of a syringe is passed through puncturable cap 80 and aspiration port 44, the needle cannot pass beyond the bottom wall of cup-shaped enclosure 88. Thus, inflatable balloon 82 is protected from the needle, but the needle can still draw the fluid which readily flows into cup-shaped enclosure 88.

Other alternative embodiments of the present invention should be apparent to those of ordinary skill in the art. For instance, flanges 12 can be provided on an element which snaps onto rigid container 10. Additional spacers, similar to spacers 31 shown in Figure 1 which slide along the wall of rigid container 10 may be provided on the handle 30" in the Figure 7 embodiment to insure uniform movement of wall 28. A self-adhesive backing may be applied to the container so that the closed wound suction device can be applied directly to the body of the patient. Also, to create a smaller negative pressure inside of rigid container 10, rigid wall 28 can be moved some distance toward open end 11 before rigid container 10 is made airtight. After rigid container 10 is made airtight, rigid wall 28 travels a smaller distance to its locked position and thus creates a smaller negative pressure.

Although the present invention has been described in detail with respect to exemplary embodiments thereof, it will be understood by those of ordinary skill in the art that variations and modifications may be effected within the scope and spirit of the invention.

CLAIMS

1. A closed wound suction device for collecting fluids comprising in combination,

a rigid container having at least a portion of one end thereof open,

closure means for said open end, said closed means being slidably movable in said container,

sealing means for providing an air tight seal between said closure means and said rigid container,

means for moving said closure means in said containers from a retracted inoperative position within the interior of said container to an extended operative position in the open end of said container wherein negative pressure is created within the interior of said rigid container and

means for locking said closure means in said extended operative position in said open end.

2. A closed wound suction device according to Claim 1 wherein said closure means comprises a rigid wall so that when said closure means is locked in the extended operative position in the open end of said rigid container the suction device comprises a completely rigid enclosure.

3. A closed wound suction device according to Claim 1 wherein port means is provided on said rigid container for connection with a drainage tube.

4. A closed wound suction device according to Claim 1 and further including a removable pull tab on said closure means for moving said closure means to the extended operative position thereof.

5. A closed wound suction device according to Claim 1 wherein said locking means comprise resilient elements on said closure means and recesses on said container adapted to receive said resilient elements.

6. A closed wound suction device according to Claim 1 wherein said container comprises an integrally formed end wall and sidewall structure with an open end opposite said end wall, said integrally formed end

wall having port means for connecting said rigid container with a drainage tube.

7. A closed wound suction device according to Claim 1 and further including a suction indicating means.

8. A closed wound suction device according to Claim 1 and further including a resilient balloon, located inside of said rigid container, which is in fluid communication with the open atmosphere such that as said closure means is moved to create a negative pressure within the interior of said rigid container, said balloon inflates due to the atmospheric pressure whereby a smaller negative pressure is maintained in said container as said balloon resiliently seeks to return to the original uninflated position of said balloon.

9. A closed wound suction device according to Claim 1 and further including an aspiration port with a puncturable seal through which a sample of the fluid inside said container can be easily removed.

10. A closed wound suction device comprising a container having rigid side walls, a rigid end wall and an open end, said container having a curved side wall to conform to the body of a user, a movable closure slidably disposed in said container, removable means for sliding said closure from an inoperative position inside of said container to an outer operative position away from the interior of said container, means for locking said closure in the outer locked position thereof, and inflatable means disposed within said container for reducing the degree of negative pressure within the container produced by moving said closure to the operative locked position and port means for placing the interior of said container in fluid communication with a closed wound for withdrawing fluids therefrom.

FIG. 1

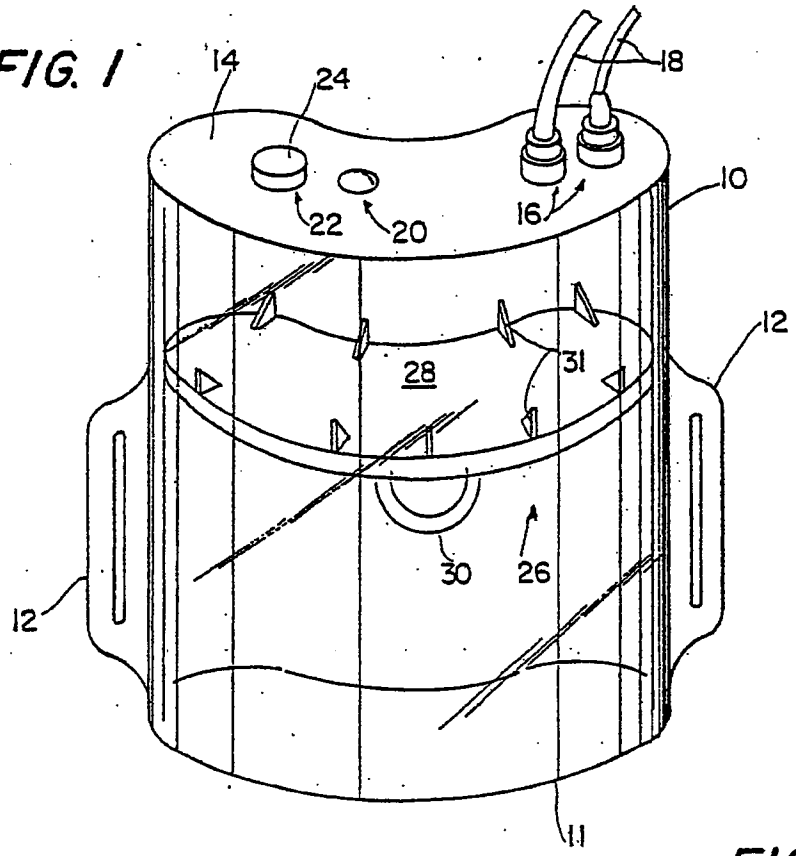


FIG. 5

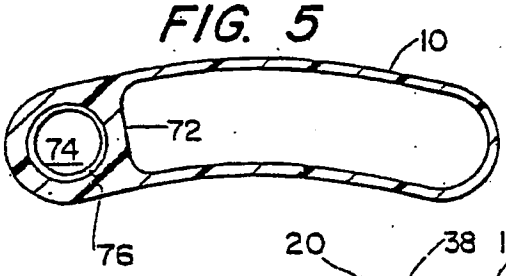
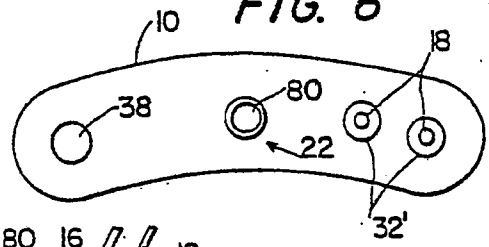


FIG. 6



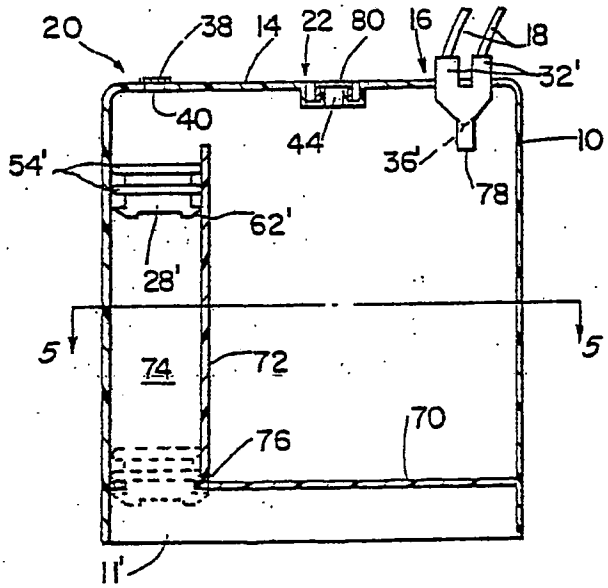


FIG. 2

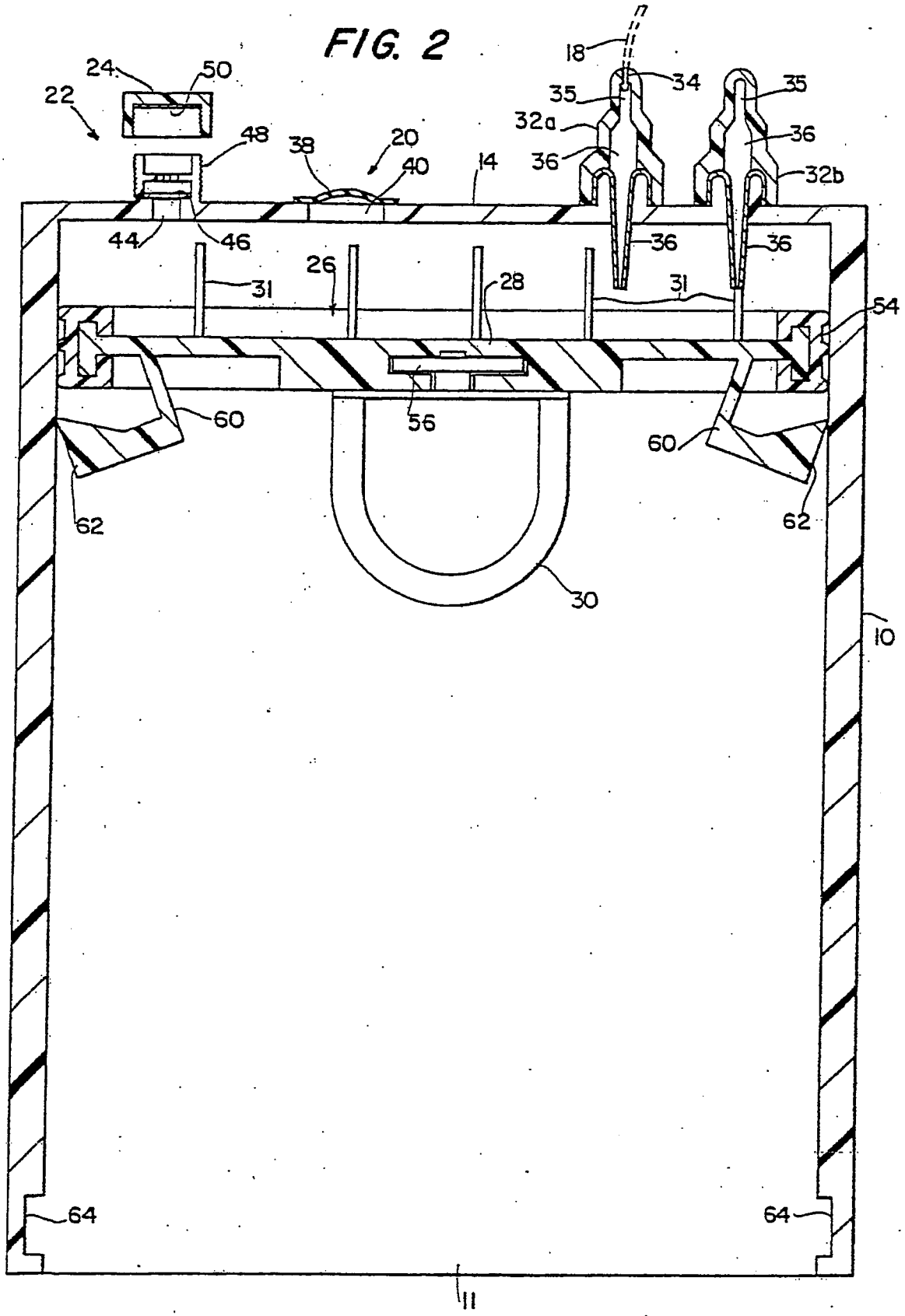
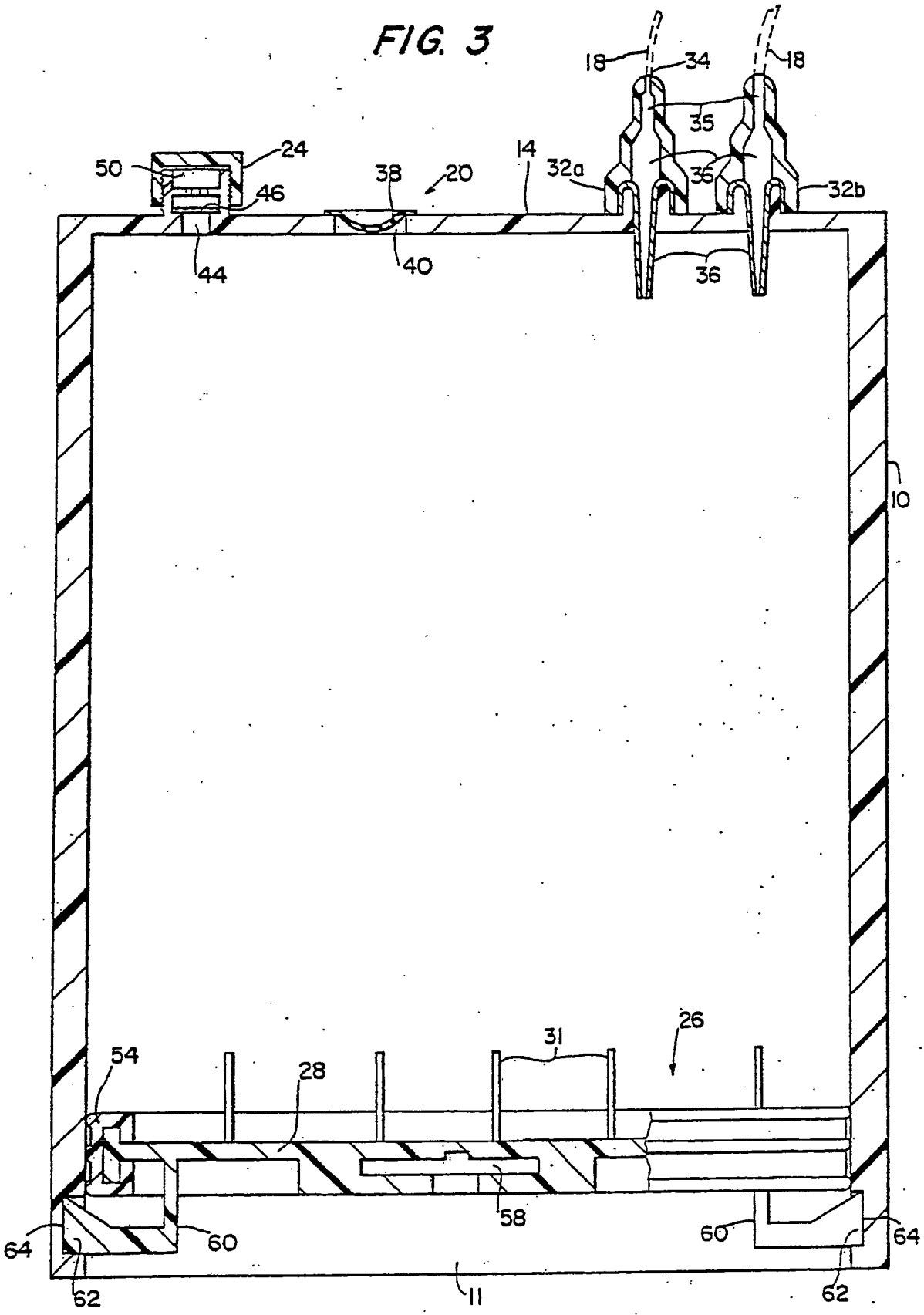


FIG. 3



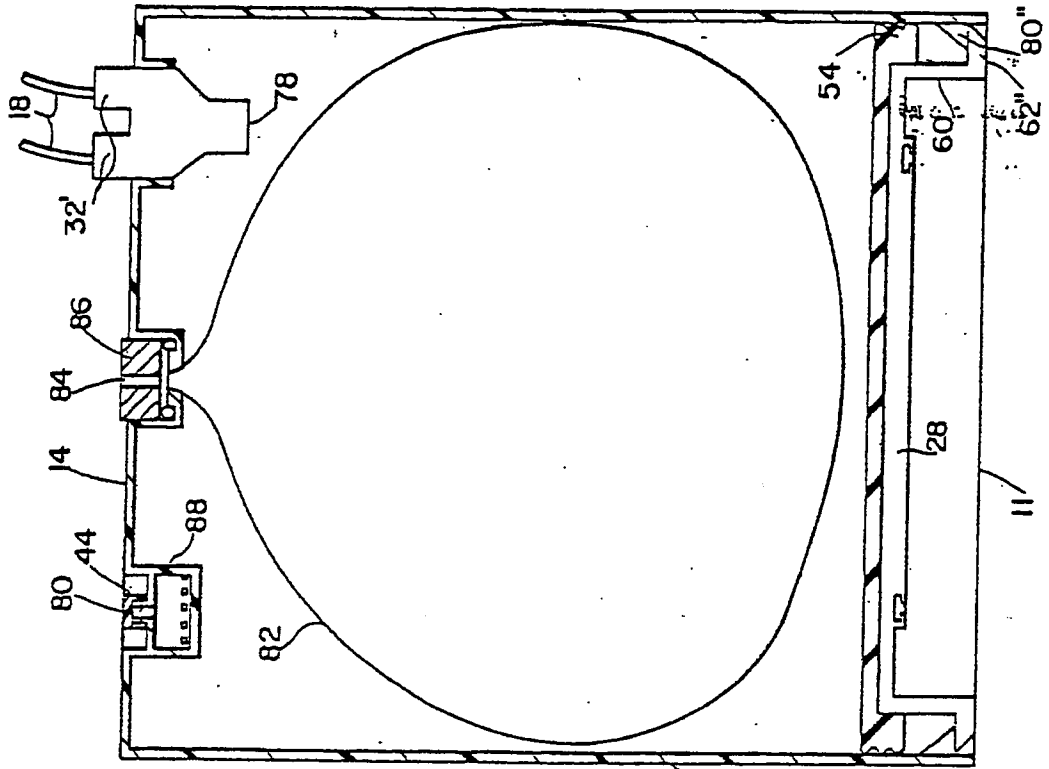


FIG. 8

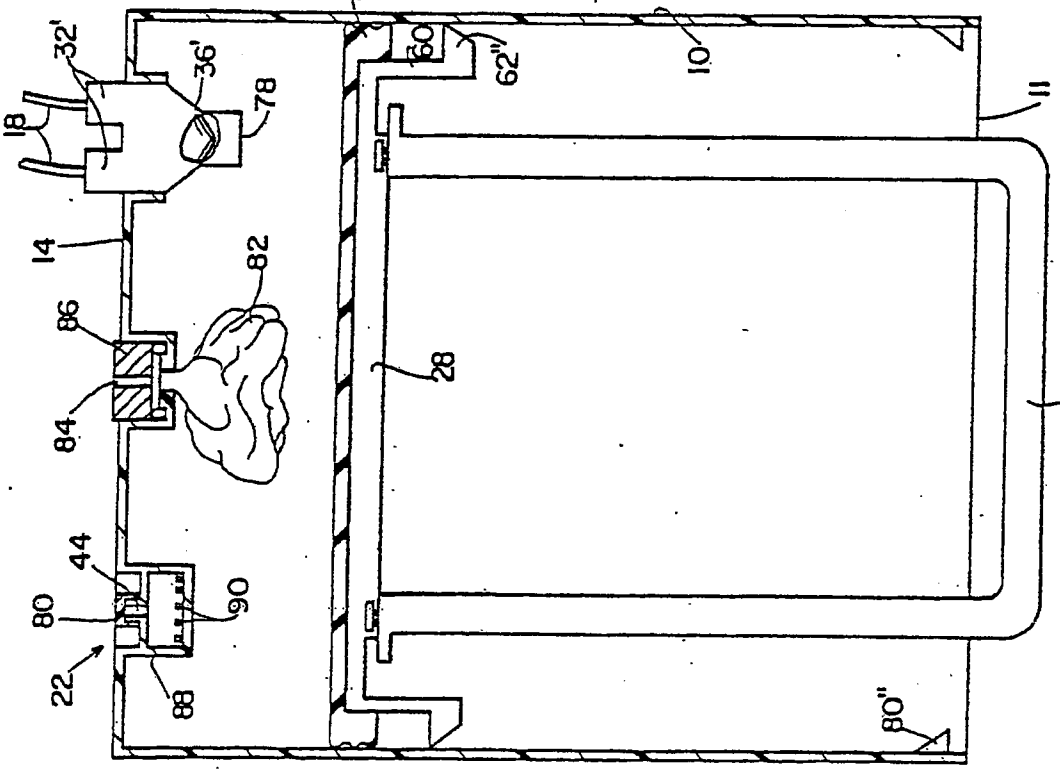


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No PCT/US80/00359

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

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II. FIELDS SEARCHED

Minimum Documentation Searched [4]	
Classification System	Classification Symbols
U.S.	128/276, 278, 763, 765, 766, 767

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	US, A, 4,112,949 Published 12 September 1978 Rosenthal et al	1, 2, 3, 4, 5, 6, 7, 8, 9
X	US, A, 3,469,578 Published 30 September 1969 Bierman	10
X	US, A, 3,032,037 Published 01 May 1962 Huber	8
A	US, A, 2,074,223 Published 16 March 1937 Horiuchi	8
A	US, A, 3,939,830 Published 24 February 1976 da Costa	1
X	US, A, 3,809,086 Published 07 May 1974 Schachet et al	1, 2, 4, 7
X	US, A, 3,785,367 Published 15 January 1974 See Figs. 4-6, Fortin et al	8
A	US, A, 3,527,215 Published 08 September 1970 De Witt	8
X	US, A, 3,951,146 Published 20 April 1976, Chiquiar-Arias	2, 5
X	US, A, 3,543,753 Published 01 December 1970 Weinstein	10

* Special categories of cited documents: [15]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
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International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	J. Kruter

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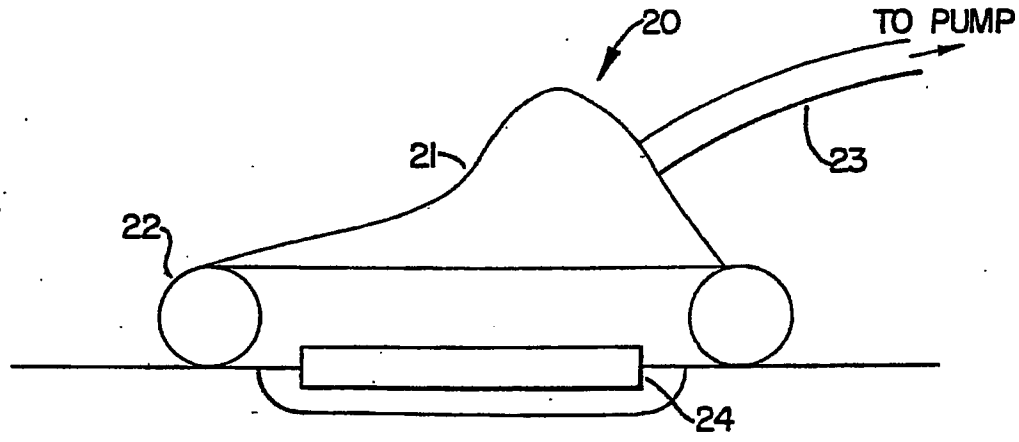
(54) Title: METHOD AND APPARATUS FOR TREATING TISSUE DAMAGE



(57) Abstract

The invention disclosed is a method of treating tissue damage comprising applying a negative pressure to a wound sufficient in time and magnitude to promote tissue migration and thus facilitate closure of the wound. The method is applicable to wounds, burns, infected wounds, and live tissue attachments. Configurations of apparatus for carrying out the method are also disclosed

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METHOD AND APPARATUS FOR TREATING TISSUE DAMAGE

Field of the Invention

This invention relates generally to wound healing, and more specifically is directed at wounds that are unlikely to heal completely under conventional methods.

Background of the Invention

The treatment of open wounds that are too large to spontaneously close has been a troublesome area for many years. Wound closure requires that epithelial and subcutaneous tissue adjacent to the wound migrate toward and eventually close the wound. Some wounds are sufficiently large or infected that they are unable to close spontaneously. In such instances, a zone of stasis, an area in which localized swelling of tissues restricts the flow of blood to these tissues, forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and accordingly is unable to close spontaneously.

The most common technique for closure of open wounds has long been the use of sutures or staples. These mechanical closure methods provide tension on the skin tissue at the wound border that encourages

epithelial tissue to migrate toward the wound and cover it. While suturing and stapling of wounds is widely practiced, it has a major drawback: the tensile force required to achieve closure with sutures or staples causes very high localized stresses at the suture insertion points, resulting in the rupture of the tissue at these points. Substantial rupture will eventually cause dehiscence in some wounds, which results in additional tissue loss. Moreover, some infected wounds harden and inflame to such a degree that closure by suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high costs, and major surgical procedures, such as grafts of surrounding tissue. Examples of such wounds include large, deep, open wounds, pressure sores resulting from prolonged pressure, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

To date, there has been no consistently satisfactory method for treating such wounds. What is needed is a method of closing the wound without the localized stresses that accompany suturing while at the same time treating any infection present in the wound along with a simple apparatus to carry out the method. Such a method and apparatus would reduce hospitalization and increase the probability of wound closure.

Summary of the Invention

A first aspect of the invention is a method of treating tissue damage which comprises applying a negative pressure to a wound over an area sufficient to promote the migration of epithelial and subcutaneous tissue toward the wound and for a time period sufficient to facilitate closure of the wound. The method is particularly useful for treating pressure sores.

A second aspect of the invention is a method of treating a burn wound which comprises applying a negative pressure to the burn over an area and for a time sufficient to inhibit progression in the depth of the burn. The method is preferably used on a partial thickness burn soon after its infliction.

A third aspect of the invention is a method of treating tissue damage which comprises applying a negative pressure to a wound for a time sufficient to reduce bacterial density in a wound. A preferred use of this method is its application to a wound for at least 3 days to reduce the bacterial density of an infected wound to the point at which surgical closure can be attempted.

A fourth aspect of the invention is a method of enhancing the attachment of adjacent tissue to a wound which comprises applying a negative pressure to a joined complex of wound and adjacent living tissue at a sufficient magnitude and for a sufficient time to promote the migration of epithelial and subcutaneous tissue toward the complex. A preferred use of this method is enhanced attachment of adjacent tissue to tissues of the wound edges. Another use is enhanced attachment of an open skin graft.

A fifth aspect of the invention is an apparatus for facilitating the healing of wounds which comprises vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain the negative pressure on the wound, and screen means for preventing overgrowth of tissue in the wound area. A preferred embodiment of the invention comprises a section of open-cell foam configured to be placed over a wound, a flexible tube inserted into the foam section for attachment to a suction pump, and a flexible polymer sheet overlying the foam section and tubing and configured to be adhered to the skin surrounding the wound.

Brief Description of the Drawings

Figure 1 shows a cross-sectional view of a negative pressure device comprising a open-cell polymer screen, a flexible hose connecting the foam section to a suction pump, and a flexible polymer sheet overlying the foam-hose assembly to provide the necessary seal; and

Figure 2 shows a cross-sectional view of a negative pressure device comprising a porous screen, an inflatible cuff attached to a semi-rigid cup, and a flexible hose extending from a suction pump to a point within the sealed volume of the cup-cuff assembly.

Detailed Description of the Invention

The present invention includes a method of treating tissue damage which comprises the stages of applying a negative pressure to a wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound, with the negative pressure being maintained for a time sufficient to facilitate closure of the wound. Wound closure requires that epithelial and subcutaneous tissue migrate from the wound border toward the wound. The use of negative pressure provides tension on this border tissue that causes accelerated tissue migration. It has been observed that the use of the method also causes within the wound increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing.

The method is particularly suited for use on pressure sores. A pressure sore is a wound that develops due to constant compressive pressure on the skin surface and underlying tissue. Blood flow to the compressed tissue is restricted to the extent that the overlying tissue dies and subsequently allows the underlying tissue

to become infected. The decrease of blood flow to the wound prevents a normal immune reaction to fight the infection, the presence of which prevents tissue migration from the wound border. Pressure sores often occur on bedridden patients who are unable to feel the sore or to move sufficiently to relieve the contact pressure. Such wounds can become very serious, requiring extensive and repeated skin grafts; some are even fatal. As described above, application of negative pressure to the sore permits migration of wound border tissue to occur and thus allows sores to heal without these more drastic procedures.

The method can be practiced with the application of substantially continuous negative pressure, where the pressure is relieved only to change the dressing on the wound, or it can be practiced with the use of a cyclic application of pressure in alternate periods of application and non-application. The ratio of duration of application period to non-application period can be as low as 1:10 or as high as 10:1, but is most preferably 1:1. A preferred pattern is 5 minutes of pressure application followed by 5 minutes of relief.

The method is preferably practiced using a negative pressure ranging from 0.01 to 0.99 atmospheres, and more preferably practiced using a negative pressure ranging between 0.5 to 0.8 atmospheres. The time period for use of the method on a wound is preferably at least 12 hours, but can be, for example, 1 day, 2 days, 5 days, 7 days, 14 days, 30 days, or even longer. There is no upper limit beyond which use of the method is no longer beneficial; the method increases the rate of closure up to the time the wound actually closes.

The present invention also includes a method of treating damaged tissue which comprises the steps of applying a negative pressure to a wound for a time and at a magnitude sufficient to reduce bacterial density in the wound. Open wounds are almost always contaminated with

harmful bacteria. Generally a bacterial density of 10^5 bacterial organisms per gram of tissue is regarded as infected. (It is generally accepted that at this level of infection, grafted tissue will not adhere to a wound). These bacteria must be killed, either through the wound host's natural immune response or through some external method, before a wound will close. We have observed that application of negative pressure to a wound will reduce the bacterial density of the wound; it is believed that this effect is due to either the bacteria's incompatibility with a negative pressure environment or the increased blood flow to the wound area, as blood brings with it cells and enzymes to destroy the bacteria.

The method can be used to reduce bacterial density in a wound by at least half. More preferably, it can be used to reduce bacterial density by at least 1,000 fold. Most preferably, the method can be used to reduce bacterial density by at least 1,000,000 fold. The ranges of pressure magnitude and application duration are as described above, although Example 3 demonstrates dramatic reduction in wound contamination after a 4-day application of negative pressure. Pressure can be applied continuously or cyclically in the application/nonapplication ratios described above.

The present invention also includes a method of treating a burn which comprises the steps of applying a negative pressure to the burn over an area and for a time sufficient to inhibit formation of a full thickness burn. A partial thickness burn, one which has a surface layer of dead tissue and an underlying zone of stasis, is often sufficiently infected that it will transform within 24-48 hours into a full thickness burn, one in which all epidermal structures are destroyed. As explained above, the application of a negative pressure to the wound prevents the infection from becoming sufficiently severe to cause destruction of the underlying epidermal structures. As above, the magnitude, pattern, and

duration of pressure application can vary with the individual wound.

The present invention also provides a method for enhancing the attachment of living tissue to a wound which comprises the steps of first joining the living tissue to the wound to form a wound-tissue complex, then applying a negative pressure to the wound-tissue complex over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the complex, with the negative pressure being maintained for a time period sufficient to facilitate closure of the wound. Attachment of living tissue to a wound is a common procedure that can take many forms. For example, one common technique is the use of a "flap", a technique in which skin tissue from an area adjacent to the wound is detached on three sides but remains attached on the fourth, then is moved onto the wound. Another frequently used technique is an open skin graft in which skin is fully detached from another skin surface and grafted onto the wound. The application of negative pressure to the wound-graft complex reduces bacterial density in the complex and improves blood flow to the wound, thereby improving the attachment of the grafted tissue.

The acceptable ranges of time, magnitude, and application/non-application ratio are as described above. Each of these variables is affected by the size and type of wound.

The present invention also includes an apparatus for facilitating the healing of wounds. The apparatus comprises vacuum means such as a pump for creating a negative pressure on the area of skin surrounding the wound, sealing means such as an adhesive sheet operatively associated with the vacuum means for maintaining negative pressure on the wound by contacting the skin surrounding the wound, and screen means such as as open-cell foam section located within the sealing

means for preventing the overgrowth of tissue in the wound area.

The screen means is placed over substantially the expanse of the wound to prevent its overgrowth. The size and configuration of the screen can be adjusted to fit the individual wound. It can be formed from a variety of porous semi-rigid materials. The material must be sufficiently porous to allow oxygen to reach the wound, and sufficiently rigid to prevent wound overgrowth. Most preferred is the use of an open-cell polymer foam, which permits direct connection of the screen means to the vacuum means through a flexible hose inserted into the foam. Such foam can vary in thickness and rigidity, although it is preferred that a spongy material be used for the patient's comfort if the patient must lay upon the device during its operation. It can also be perforated to reduce its weight. Another embodiment comprises a section of honeycombed polyethylene sheet cut to the shape of the wound.

Possible sealing means include a flexible sealing rim contacting the skin surrounding the wound, a flexible polymer sheet overlying the screen means and the vacuum means and attached to the skin through an adhesive applied to the sheet surface facing the skin, and an inflatable sealing cuff that conforms to the skin when inflated and that is held in place by the suction of the vacuum means. If an adhesive sheet is used, it must have sufficient adhesion to remain in contact with the skin and form a seal under the negative pressure. Additionally, it must be sufficiently flexible to overlay the screen means and still conform to the skin around the wound. The sealing means also can include a semi-rigid cup that protects the wound from external contact. For example, a suitable cup-cuff assembly is provided by an adult CPR mask with an inflatable sleeve.

Suitable vacuum means includes any suction pump capable of providing at least 0.1 pound suction to the

wound, and preferably up to 3 pounds suction, and most preferably up to 14 pounds suction, and a flexible hose that leads from the pump to a point within the pressurized volume created by the sealing means. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the necesary suction. The dimension of the tubing are limited only by the pump's ability to provide the suction level neede for operation. A 1/4 inch diameter tube has proven suitable. The vacuum means may operate substantially continuously, or may operate cyclically with alternate periods of application and nonapplication of pressure to the wound.

A preferred embodiment of the invention, shown in Figure 1, comprises a substantially flat section of open cell polyester foam section 10 (Fischer Scientific, Pittsburgh, PA 15219) sufficiently large to cover the wound and thus prevent wound overgrowth, a flexible hollow tube 11 (Fischer Scientific) inserted into the open cell foam section 10 and joined thereto with an adhesive and extending to attach at its opposite end to a Gast Vacuum pump (Fischer Scientific), and an Ioban adhesive sheet 12 (Minnesota Mining and Manufacturing, St. Paul, MN. 55144) overlying the foam section 10 and tubing 11 and adhered to the skin surrounding the wound, thus forming a seal that allows creation of a vacuum when the suction pump operates. Such an apparatus would most preferably be packaged in a sterile condition to ameliorate the need for sterilization of the apparatus prior to use (note that the adhesive sheet 12 could be packaged separately from the foam-tube assembly). A particular advantage of this configuration is its use with pressure sores: the device can be placed in the depths of the wound and the patient can lie upon it without either affecting the utility of the device or further damaging the wound. This becomes critical if the

patient cannot be moved from this posture for other medical reasons.

The present invention is explained further in the following examples. These examples are provided for illustrative purposes only and are not to be taken as limiting.

EXAMPLE 1

Rate of Wound Healing under Negative Pressure

This example demonstrates the use of negative pressure to increase the rate of healing of full thickness defects by increasing vascularity and the amount of granulation tissue present.

Fifteen-kilogram pigs were obtained and conditioned for 1 week prior to use. The backs of the pigs were shaved and scrubbed for surgery. Two full thickness circular defects were created on the midline of the animals, 2.5 cm in diameter and 1 cm thick. Alginate impressions were taken of each defect to determine its volume. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). The suction devices used, shown in Figure 2, comprised an adult CPR mask 20 (Doug Brown and Associates, Huntington Beach, CA 92648) comprising a semi-rigid cup 21 and inflatible cuff 22 in contact with the skin, an open cell polyester screen 24 overlying the wound, and a flexible 1/4 inch diameter hose 23 (Fischer Scientific) connected by a Nalgene tubing connector to a vacuum pump (Fischer Scientific) and extending through a sealed hole in the cup. Each device was configured such that the suction hose ran from the cup on the animal up through a pulley suspended over the center of the pen and down to a vacuum trap bottle to collect any liquid exudate, then down to the vacuum pump. A suction device was attached over each defect, and suction (2-6 pounds vacuum) was applied to one of the devices. The devices were removed only so that impressions could be made of each defect. This

procedure was continued until the volume of both defects was zero.

Table 1 compares the volume of defects over time on individual specimens. Table 2 shows data expressed as the amount of granulation tissue formed per day and as the percent difference in rate of granulation tissue formation. Both data sets show that in all cases the use of negative pressure increased the rate of wound closure and the formation of granulation tissue at a statistically significant rate.

EXAMPLE 2

Rate of Burn Healing under Negative Pressure

This example was designed to demonstrate the use of continuous closed suction for the treatment of deep, partial thickness thermal burns (second degree burns).

The backs of 15 kg pigs were shaved and scrubbed for surgery. A 1.5 inch diameter brass rod was heated to 190°C in an oil bath. The rod was pressed onto the pig's skin for 15 seconds following a well-known technique of relating depth of burn to time and temperature. Three burns were created over the spine of each pig, separated by 5 cm intervals. Suction apparatus cups of the configuration described above were placed over two of the burns, with silver sulphadiazine (Silvadine) cream, the standard antibiotic cream applied to human burns prior to excision of burned tissue, applied to the third. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). Suction (2-6 pounds vacuum) was applied to one of the cups. A small (2 mm) punch biopsy was taken of the wounded area and examined histologically for depth of burn.

Table 1. Rate of granulation tissue formation for control and reduced pressure treated full thickness defects in pigs. (Day 0 = surgery)

		Defect Volume (cc)												
Animal	Treatment	Day 0	Day 1	D 2	D 3	D 4	D 5	D 6	D 7	D 8	D 9	D 10	D 11	D 12
1	Suction	5.3			4.3					0				
	Control	5.0			4.7					1.2				
2	Suction	9.3			8.0			6.5		0				
	Control	7.2			6.0			5.0		0				
3	Suction	5.0		4.0				1.5		0				
	Control	5.0		4.0				3.0		1.5		0		
4	Suction	7.0				6.0		2.0		0				
	Control	7.0				6.0		4.0		2.0		0		
5	Suction	6.0				5.0		1.0		0				
	Control	6.0				6.0		3.0		2.0		0		

Table 2. Rate of granulation tissue formation for control and reduced pressure treated full thickness defects in pigs.

Animal	Granulated Treatment	Tissue/Day(cc)	% Increase*
1	Suction	0.48	26.3
	Control	0.38	
2	Suction	1.16	28.9
	Control	0.90	
3	Suction	0.58	75.8
	Control	0.33	
4	Suction	0.71	65.1
	Control	0.43	
5	Suction	0.71	65.1
	Control	0.43	

* (Suction-Control)/Control

Table 3. Rate of reduction in bacterial density for control and reduce and pressure treated pigs (n=5).

Log Organisms Per Gram Tissue

eatment	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 7
ntrol	Mean 8.44	8.04	8.17	7.13	7.13	8.82	7.08
	SD +.38	±.13	±.98	±.15	±.24	±1.12	±.52
cuum	Mean 7.69	7.36	7.37	6.79	6.43	3.98	4.32
	SD ±.83	±.84	±1.40	±.55	±.45	±3.46	±3.74

Biopsies were analyzed by a dermatopathologist who was not told the nature of the study. It was concluded that the suctioned tissue specimens were healthier and healing more quickly than non-suctioned specimens.

EXAMPLE 3

Reduction of Bacterial Density under Negative Pressure

This example illustrates the effects of continuous closed suction on the bacterial density of infected tissue.

Fifteen-kilogram pigs were shaved and prepared for surgery. Two 2.5 cm diameter defects were created on the dorsum of each pig using sterile technique, with a 7.5 cm interval retained between the edges of the defects. Hemostasis was obtained by electrocautery. One ml of culture broth containing 10^8 Staph. aureus organisms was injected just beneath the surface tissue in the center of each wound. Suction cups of the configuration described above were placed over each defect, and a T-shirt was placed over the animal. Suction (2-6 pounds vacuum) was applied 24 hours after surgery to only one of the defects, allowing each animal to act as its own control. No antibiotics were given during the course of the study.

Each day, a small (3 mm biopsy punch) piece of granulation tissue was removed from the center of each defect. The number of organisms present in the tissue was determined by weighing the tissue, homogenizing the tissue, serially diluting the supernatant, and plating the diluted supernatant on blood agar plates. Samples of the original broth were treated in an identical manner to determine effects of mechanical manipulations on bacteria viability. The procedure was performed until the wounds were healed.

Table 3 compares the bacterial density of treated wounds and control wounds over time. The data is expressed as the mean log of the number of viable organisms per gram of tissue as a function of time. Clearly, the application of negative pressure increases the rate at which bacteria are destroyed. Using 10^5 organisms per gram of tissue as a baseline for infection, the data show that on average a suctioned wound was disinfected after 4 days of treatment, while the average non-treated wound was still infected after 7 days.

EXAMPLE 4

Treatment of Pressure Sore With Negative Pressure

Mr. L.J. is a 45-year-old diabetic male who has been a paraplegic as the result of a gunshot wound for 12 years. He has a history of recurrent right ischeal fossa pressure sore and right trochanteric pressure ulcer. L.J. was admitted to the hospital for treatment and closure of the pressure sores. A flap was placed onto the wound and secured with sutures and staples.

The incisions of the flap dehisced, resulting in a large, open wound. The tissues of the flap were very edematous and indurated. Nine days after the flap was detached, a negative pressure device was placed over the wound. The device comprised an open-cell polyester foam section (Fischer Scientific) approximately 1/2 inch in thickness attached to a suction pump by a flexible hose (Fischer Scientific) and covered and sealed by Ioban polymer sheet (Minnesota Mining and Manufacturing, St. Paul, MN 55144). A continuous vacuum of 5 psi was applied to the wound. The design of the device allowed the patient to lay comfortably on the device during operation.

The depth of the wound decreased dramatically. The devices were changed and the wound examined on a three times per week basis. Reduced pressure treatment

was continued for 6 weeks, at which time the wound was healed.

EXAMPLE 5

Treatment of Pressure Sore With Negative Pressure

Mr. W.E. is a 51-year-old male who had both legs amputated at the hip approximately 20 years ago. He was afflicted with a large pressure sore in the buttocks region. The pressure sore had been present 7 months and measured 8 inches laterally and 3 inches in its greatest width. An open cell foam reduced pressure device as described in Example 4 was placed over the wound and a negative pressure of 5 psi was applied cyclically in alternate periods of 5 minutes on, 5 minutes off. The open cell foam device was used as the patient was lying on the device. The device was changed on a three times per week schedule.

After 5 weeks of treatment, the wound measured 3 inches laterally and 1.5 inches at its greatest width. At that point the wound was essentially healthy granulation tissue that accepted a cultured keratinocyte allograft and healed completely.

EXAMPLE 6

Treatment of Wound Dehiscence With Negative Pressure

Mr. C.L. is a 50-year-old male who had undergone a colostomy revision through a midline laparotomy. He was readmitted to the hospital for wound dehiscence and evisceration following forceful coughing. The abdominal wall was closed with Prolene mesh coverage. Six weeks after placement of the Prolene mesh, the wound was still open and measured 28 cm by 23 cm with sparse granulation tissue grown through the Prolene mesh. A large reduced pressure cup device of the type described in Example 1 with an underlying porous Aquaplast sheet

(WFR/Aquaplast Corp., Wyckoff, NJ 07481) was placed on the Prolene mesh/wound surface and the space closed with a tent of Ioban. Five psi of continuous negative pressure was applied. The device was changed three times per week.

After 6 days, granulation tissue had grown through the Prolene mesh, totally covering the mesh. The patient was taken to the operating room where the surrounding tissue was undermined and grafted onto the wound to partially close the defect. Split thickness skin grafts were used to cover the remainder of the defect, and were placed on the bed of granulation tissue. The wound accepted 80 % of the grafts, and the remaining areas closed with dressing changes alone.

EXAMPLE 7

Treatment of Ankle Osteomyelitic Ulcer With Negative Pressure

Mr. R.F. is a 39-year-old white male who had severe trauma to his left lower extremity secondary to a motor vehicle accident 10 years ago. He had contracted chronic osteomyelitis and an open ulcer with exposed bone of his left lateral ankle (lateral malleolar ulcer). Necrotic soft tissue and bone were surgically removed from the ankle. The patient was placed on a 2-1/2 week course of antibiotics. The day after surgery, a reduced pressure device of the type described in Example 1 was placed over the wound, and a negative pressure of 5 psi was applied. The device was changed on a three times per week schedule. After 14 days of treatment, the wound was smaller and filled with granulation tissue. A split thickness skin graft was placed over the center of the defect and healed primarily.

EXAMPLE 8

Treatment of Burn With Negative Pressure

Patient B. is admitted with second and third degree burns over the face and upper extremities, including both hands, as a result of a house fire. A large mitten-shaped reduced pressure device of the type described in Example 4 is placed over the patient's right hand, with open cell foam inserts placed between the fingers to apply reduced pressure to the interdigit spaces. Three pounds of vacuum is applied cyclically in a pattern of 5 minutes on, 5 minutes off. The device is changed on a three times per week schedule. Treatment is continued until the necrotic tissue sloughs off or is excised, followed by split thickness skin graft placement.

The foregoing examples are illustrative of the present invention, and are not to be construed as limiting thereof. The invention is defined by the following claims, with equivalents of the claims to be included therein.

THAT WHICH IS CLAIMED IS:

1. A method of treating tissue damage which comprises the steps of:

applying a negative pressure to a wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound, with said negative pressure being maintained for a time sufficient to facilitate closure of the wound.

2. A method according to claim 1, in which said negative pressure is maintained for a time sufficient to permit the formation of granulation tissue in the wound.

3. A method according to claim 1, in which said wound is a pressure sore.

4. A method according to claim 1, in which said negative pressure is between 0.01 and 0.99 atmospheres.

5. A method according to claim 1, in which said negative pressure is between 0.5 and 0.8 atmospheres.

6. A method according to claim 1, in which said time is at least 12 hours.

7. A method according to claim 1, in which said time is at least 3 days.

8. A method according to claim 1, in which said pressure is applied substantially continuously.

9. A method according to claim 1, in which said negative pressure is cyclically applied in alternate periods of application and non-application.

10. A method according to claim 9, in which the ratio of said period of application to said period of non-application is at least 10:1.

11. A method according to claim 9, in which the ratio of said period of application to said period of non-application is at least 1:1.

12. A method according to claim 9, in which the ratio of said period of application to said period of non-application is at least 1:10.

13. A method of treating a burn which comprises the steps of:

applying a negative pressure to said burn for a time sufficient to inhibit formation of a full thickness burn.

14. A method according to claim 13, in which said burn is a partial thickness burn.

15. A method according to claim 13, in which said time is at least 12 hours.

16. A method according to claim 13, in which said time is at least 3 days.

17. A method according to claim 13, in which said negative pressure is between 0.01 and 0.99 atmospheres.

18. A method according to claim 13, in which said negative pressure is between 0.5 and 0.8 atmospheres.

19. A method according to claim 13 in which said negative pressure is applied substantially continuously.

20. A method according to claim 13, in which said negative pressure is cyclically applied in alternate periods of application and non-application.

21. A method according to claim 20, in which the ratio of said period of application to said period of non-application is at least 10:1.

22. A method according to claim 20, in which the ratio of said period of application to said period of non-application is at least 1:1.

23. A method according to claim 20, in which the ratio of said period of application to said period of non-application is at least 1:10.

24. A method of treating damaged tissue which comprises the steps of:

applying a negative pressure to a wound at a magnitude and for a time sufficient to reduce bacterial density in said wound.

25. A method according to claim 24, in which said bacterial density is reduced by at least half.

26. A method according to claim 24, in which said bacterial density is reduced by at least 1,000 fold.

27. A method according to claim 24, in which said bacterial density is reduced by at least 100,000 fold.

28. A method according to claim 24, in which said negative pressure is applied for at least 12 hours.

29. A method according to claim 24, in which said negative pressure is cyclically applied in alternate periods of application and non-application.

30. A method according to claim 24, in which said negative pressure is applied at between 0.01 and 0.99 atmospheres.

31. A method of enhancing the attachment of living tissue to a wound which comprises the steps of:

joining said living tissue to said wound to form a wound-tissue complex, and

applying a negative pressure to said wound-tissue complex over an area sufficient to promote migration of epithelial and subcutaneous tissue toward said complex, with said negative pressure being maintained for a time period sufficient to facilitate closure of the wound.

32. A method according to claim 31, in which said living tissue to be attached is a skin graft.

33. A method according to claim 31, in which said living tissue is a flap formed from adjacent tissue.

34. A method according to claim 31, in which said negative pressure is applied for at least 12 hours.

35. A method according to claim 31, in which said negative pressure is cyclically applied in alternate periods of application and non-application.

36. A method according to claim 31, in which said negative pressure is applied at between 0.01 and 0.99 atmospheres.

37. An apparatus for facilitating the healing of wounds, comprising:

vacuum means for creating a negative pressure on the area of skin including and surrounding the wound; and

sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound.

38. An apparatus according to claim 37, which further includes screen means connected to said vacuum means for preventing the overgrowth of tissue in the wound area.

39. An apparatus according to claim 37, in which said screen means is a structure comprised of an open-cell polymer foam.

40. An apparatus according to claim 37, in which said screen means is a flat, porous, semi-rigid member.

41. An apparatus according to claim 37, in which said sealing means includes a flexible sealing rim in contact with said skin surrounding said wound.

42. An apparatus according to claim 37, in which said sealing means is a flexible polymer sheet overlying said screen means and said vacuum means, said polymer sheet having adhesive on at least the surface facing the wound to attach and seal said polymer sheet to said surrounding skin.

43. An apparatus according to claim 37, in which said sealing means includes a sealing cuff in contact with said skin surrounding the wound.

44. An apparatus according to claim 43, in which said sealing cuff is inflatable.

45. An apparatus according to claim 37 in which sealing means includes a semi-rigid cup configured to protect said wound from external contact.

46. An apparatus according to claim 37, in which said vacuum means includes pump means capable of providing at least 0.1 pounds suction.

47. An apparatus according to claim 37, in which said vacuum means includes a pump means capable of providing at least 3 pounds suction.

48. An apparatus according to claim 37, in which said vacuum means includes a pump means capable of providing at least 14 pounds suction.

49. An apparatus according to claim 37, in which said vacuum means operates continuously.

50. An apparatus according to claim 37, in which said vacuum means operates cyclically to provide periods of application and non-application of suction.

51. An apparatus for facilitating the healing of wounds comprising:

an open cell polymer foam section configured to overlie a wound; and

a flexible tube having an inlet end and an outlet end, said inlet end inserted into said open cell polymer foam section.

52. An apparatus according to claim 50, which is in an aseptic package.

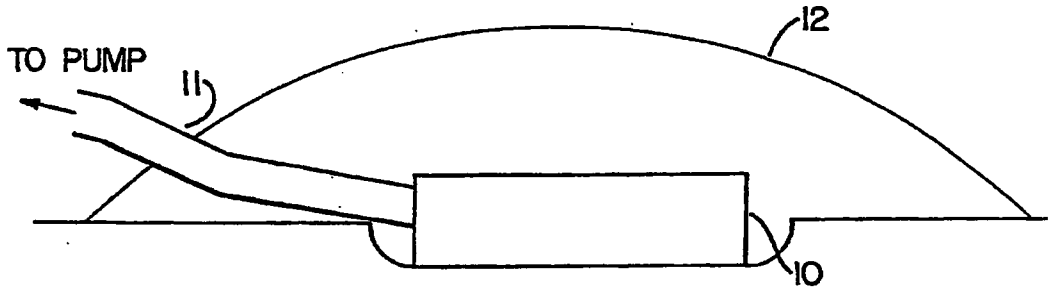

FIG. 1.

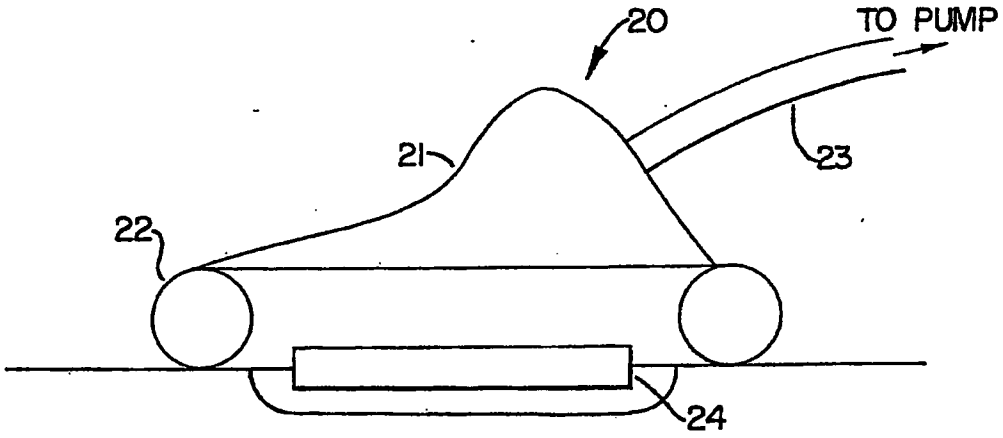

FIG. 2.

INTERNATIONAL SEARCH REPORT

PCT/US92/09649

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 19/00;
US CL :128/898

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898 128/897-899 602/42-53

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A, 3,874,387 (Barbieri) 01 April 1975 See entire document.	37,41,43
X	US,A, 4,382,441 (Svedman) 10 May 1983 See entire document.	51
A	US,A, 3,367,332 (Groves) 06 February 1968 See entire document.	1-52
A	US,A, 3,026,874 (Stevens) 27 March 1962 See entire document.	1-52
A	US,A, 3,896,810 (Akiyama) 29 July 1975 See entire document.	1-52

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 28 DECEMBER 1992	Date of mailing of the international search report 25 : -
Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer JOHN LACYK Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/09649

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 3,954,105 (Nordby et al.) 04 May 1976 See entire document.	1-52
A	US,A, 4,112,947 (Nehring) 12 September 1978 See entire document.	1-52
A	4,224,945 (Cohen) 30 September 1980 See entire document.	1-52
A	US,A, 4,250,882 (Adair) 17 February 1981 See entire document.	1-52
A	US,A, 4,834,110 (Richard) 30 May 1989 See entire document.	1-52